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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.

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3. The important elements of typical Federal Register documents.

4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, March 18, 2008
9:00 a.m.–Noon

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

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Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

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Presidential Documents

Title 3—

The President

Executive Order 13459 of February 7, 2008

Improving the Coordination and Effectiveness of Youth Programs

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in recognition of the successful interagency collaboration resulting from the *Helping America's Youth* initiative, it is hereby ordered as follows:

Section 1. *Policy*. It is the policy of the Federal Government to promote achievement of positive results for at-risk youth through:

(a) enhanced collaboration among government organizations at the Federal, State, and local level, including with faith-based and other community organizations, as well as among families, schools, and communities, in order to leverage existing resources and improve outcomes;

(b) identification and dissemination of promising strategies and practices that have been proven effective through rigorous evaluation; and

(c) online publication of essential information to assist interested citizens and decision-makers, particularly at the community level, to plan, implement, and participate in effective programs for at-risk youth.

Sec. 2. *Establishment of the Interagency Working Group on Youth Programs*. The Secretary of Health and Human Services (Secretary) shall establish within the Department of Health and Human Services for administrative purposes only, an Interagency Working Group on Youth Programs (Working Group), consistent with this order and reflecting the ongoing interagency collaboration under the *Helping America's Youth* initiative.

Sec. 3. *Membership and Operation of the Working Group*.

(a) The Working Group shall consist exclusively of the following members or their designees, who shall be full-time Federal officers or employees:

(i) the Secretary;

(ii) the Attorney General;

(iii) the Secretaries of Defense, the Interior, Agriculture, Commerce, Labor, Housing and Urban Development, and Education;

(iv) the Director of the Office of National Drug Control Policy;

(v) the Chief Executive Officer of the Corporation for National and Community Service; and

(vi) other officers or full-time or permanent part-time employees of the United States, as determined by the Secretary, with the concurrence of the head of the department or agency concerned.

(b) The Secretary (or the Secretary's designee) shall serve as Chair, and the Attorney General (or the Attorney General's designee) shall serve as Vice Chair, for a period of 2 years from the date of this order. Subsequent Chairs and Vice Chairs shall be designated by the Secretary on a biennial basis.

(c) In implementing this section, the Chair, and in the Chair's absence the Vice Chair, shall convene and preside at meetings of the Working Group, determine its agenda, direct its work, and establish and direct subgroups of the Working Group, as appropriate, to deal with particular subject matters, that shall consist exclusively of members of the Working Group or their

designees. The Chair, after consultation with the Vice Chair, shall designate an officer or employee of one of the member departments or agencies to serve as the Executive Secretary of the Working Group. The Executive Secretary shall head any staff assigned to the Working Group and any subgroups thereof, and such staff shall consist exclusively of full-time or permanent part-time Federal employees.

Sec. 4. *Functions of the Working Group.* Consistent with the policy set forth in section 1 of this order, the Working Group shall:

(a) identify and engage key government and private or nonprofit organizations that can play a role in improving the coordination and effectiveness of programs serving and engaging youth, such as faith-based and other community organizations, businesses, volunteers, and other key constituencies;

(b) develop a new Federal website on youth, built upon the *Community Guide to Helping America's Youth*, with the first phase of this website to be launched within 10 months of the date of this order, by:

(i) identifying and assessing the strengths and weaknesses of existing Federal websites focusing on youth-serving entities in order to improve access to the most useful content;

(ii) providing for training to youth-serving entities to enable effective use of the Federal website;

(iii) developing additional strategies and tools and resources accessible through the Federal website that will help promote effective community-based efforts to reduce the factors that put youth at risk and the provision of high-quality services to at-risk youth across the country; and

(iv) developing strategies to ensure that the Federal website is routinely updated, improved, and publicized;

(c) encourage all youth-serving Federal and State agencies, communities, grantees, and organizations to adopt high standards for assessing program results, including through the use of rigorous impact evaluations, as appropriate, so that the most effective practices can be identified and replicated, and ineffective or duplicative programs can be eliminated or reformed;

(d)(i) identify and promote initiatives and activities that merit strong interagency collaboration because of their potential to offer cost-effective solutions to achieve better results for at-risk youth, including volunteer service in concert with the USA Freedom Corps and mentoring in concert with the Federal Mentoring Council; and,

(ii) encourage rigorous evaluations, as appropriate, of such initiatives and activities to ascertain their effectiveness in improving academic, employment, social, and other individual outcomes, and make these findings publicly available, and

(e) annually report to the President, through the Assistant to the President for Domestic Policy, on its work and on the implementation of any recommendations arising from its work, with the first such report to be submitted no later than 6 months after the date of this order.

Sec. 5. *Administration of the Working Group.* (a) The Secretary shall, to the extent permitted by law, provide administrative support and funding for the Working Group.

With the consent of the Secretary, other member departments or agencies may provide administrative support to the Working Group, to the extent permitted by law and consistent with their statutory authority.

(b) The heads of executive departments and agencies shall provide, as appropriate, such assistance and information as the Secretary may request to implement this order.

(c) The website referred to in section 4(b) of this order shall be funded by contributions from executive departments and agencies to the extent permitted by law and consistent with their statutory authority.

Sec. 6. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to a department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

THE WHITE HOUSE,
February 7, 2008.

[FR Doc. 08–658
Filed 2–11–08; 8:45 am]
Billing code 3195–01–P

Rules and Regulations

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DEPARTMENT OF AGRICULTURE

Rural Housing Service

7 CFR Part 1951

Form RD 1951–33, ''Reamortization Request''

AGENCY: Rural Housing Service, USDA.

ACTION: Final rule.

SUMMARY: The Rural Housing Service (RHS) hereby amends the regulation utilized to service the Community Facilities loan and grant programs and the Business Programs direct loan program by revising the form number for reamortization requests. The form was mistakenly made obsolete during the implementation of regulations changes for the Multi-Family Housing program. This final rule will correct the form reference.

DATES: *Effective Date:* February 12, 2008.

FOR FURTHER INFORMATION CONTACT: Beth Jones, Community Programs Senior Loan Specialist, Rural Housing Service, U.S. Department of Agriculture, STOP 0787, 1400 Independence Ave., SW., Washington, DC 20250–0787, telephone: (202) 720–1498.

SUPPLEMENTARY INFORMATION:

Classification

This rule is not a significant regulatory action as defined in Executive Order 12866 and, therefore, publication for public notice and comment is unnecessary.

Programs Affected

The Catalog of Federal Domestic Assistance Program impacted by this action is 10.766, Community Facilities Loans and Grants.

Intergovernmental Review

This program is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. RHS conducts intergovernmental consultations for each loan in the manner delineated in 7 CFR part 3015, subpart V.

Civil Justice Reform

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. In accordance with this rule: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings of the National Appeals Division (7 CFR part 11) must be exhausted before bringing suit in court challenging action taken under this rule.

Environmental Impact Statement

The action has been reviewed in accordance with 7 CFR part 1940, subpart G, ''Environmental Program.'' The Agency has determined that this action does not constitute a major Federal action significantly affecting the quality of the human environment and, in accordance with the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*, an Environmental Impact Statement is not required.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, established requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, RHS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, or tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires RHS to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) for State, local, and tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Regulatory Flexibility Act

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612). The undersigned has determined and certified by signature of this document that this rule will not have a significant economic impact on a substantial number of small entities since this rulemaking action does not involve a new or expanded program.

Federalism

The policies contained in this rule do not have any substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Nor does this rule impose substantial direct compliance costs on State and local governments. Therefore, consultation with the States is not required.

Implementation

It is the policy of this Department that rules relating to public property, loans, grants, benefits, or contracts shall comply with 5 U.S.C. 553, notwithstanding the exemption of that section with respect to such rules.

Paperwork Reduction Act

The information collection and record keeping requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under OMB control number 0575–0066.

E-Government Act Compliance

The Rural Housing Service is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Discussion

The reference to ''Form RD 3560–15'' in 7 CFR 1951.223(b)(4) and (c)(3) was originally ''Form RD 1951–33.'' Form RD 1951–33 was mistakenly made obsolete and replaced with Form RD 3560–15, when revisions were implemented for the Multi-Family Housing program. This final rule will

change the form reference, in the regulation, back to Form RD 1951–33, which is the form used to process reamortizations for Community Facility loans.

List of Subjects in 7 CFR Part 1951

Accounting servicing, Grant programs—Housing and community development, Reporting requirements, Rural areas.

■ Therefore, Chapter XVIII, Title 7, Code of Federal Regulations, is amended as follows:

PART 1951—SERVICING AND COLLECTIONS

■ 1. The authority citation for part 1951 continues to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1932; 7 U.S.C. 1989; 31 U.S.C. 3716; 42 U.S.C. 1480.

Subpart E—Servicing of Community and Direct Business Programs Loans and Grants

■ 2. Section 1951.223 is amended by revising the words ''Form RD 3560–15'' to ''Form RD 1951–33'' in paragraphs (b)(4) and (c)(3).

Dated: January 25, 2008.

Russell T. Davis,

Administrator, Rural Housing Service.

[FR Doc. E8–2538 Filed 2–11–08; 8:45 am]

BILLING CODE 3410–XV–P

FARM CREDIT ADMINISTRATION.

12 CFR Part 620

RIN 3052–AC37

Disclosure to Shareholders; Annual Report to Shareholders; Effective Date

AGENCY: Farm Credit Administration.

ACTION: Notice of effective date.

SUMMARY: The Farm Credit Administration (FCA) published a final rule under part 620 on December 4, 2007 (72 FR 68060). This final rule amends our regulations to allow Farm Credit System institutions 90 calendar days to prepare and distribute annual reports to shareholders while retaining the 75 calendar day requirement for electronic reporting and distribution to the FCA. In accordance with 12 U.S.C. 2252, the effective date of the final rule is 30 days from the date of publication in the **Federal Register** during which either or both Houses of Congress are in session. Based on the records of the sessions of Congress, the effective date of the regulations is February 6, 2008.

DATES: *Effective Date:* The regulation amending 12 CFR part 620 published on December 4, 2007 (72 FR 68060) is effective February 6, 2008.

FOR FURTHER INFORMATION CONTACT: Christopher D. Wilson, Policy Analyst, Office of Regulatory Policy, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4414, TTY (703) 883–4434; or Bob Taylor, Attorney Advisor, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4020.

(12 U.S.C. 2252(a)(9) and (10))

Dated: February 6, 2008.

Roland E. Smith,

Secretary, Farm Credit Administration Board.

[FR Doc. 08–607 Filed 2–11–08; 8:45 am]

BILLING CODE 6705–01–M

Proposed Rules

Federal Register
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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL RESERVE SYSTEM

12 CFR Parts 204 and 209

[Regulations D and I; Docket No. R–1307]

Reserve Requirements of Depository Institutions; Issue and Cancellation of Federal Reserve Bank Capital Stock

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice of proposed rulemaking; request for public comment.

SUMMARY: The Board is publishing for comment proposed amendments to Regulation D (Reserve Requirements of Depository Institutions) and Regulation I (Issue and Cancellation of Federal Reserve Bank Capital Stock). Of these, only two are intended to represent substantive changes from existing law, while the remaining amendments are intended principally as clarifications. The first of the proposed substantive amendments would amend Regulation D to implement Section 603 of the Financial Services Regulatory Relief Act of 2006 by authorizing member banks of the Federal Reserve System to enter into pass-through arrangements. Previously, member banks were statutorily prohibited from passing required reserve balances through a correspondent institution. The second of the proposed substantive amendments would eliminate the provision in the ''savings deposit'' definition of Regulation D limiting certain kinds of transfers from savings deposits to not more than three per month. As a result, all kinds of transfers and withdrawals from a savings deposit that must be limited in number per month would be subject to the same numeric limitation of not more than six per month. The remaining proposed amendments, intended as clarifications, would reorganize the provisions relating to deposit reporting and the calculation and maintenance of required reserves, clarify the definitions of ''time deposit'' and ''vault cash,'' and make other minor editorial changes.

DATES: Comments must be received on or before March 28, 2008.

ADDRESSES: You may submit comments, identified by Docket No. R–1307, by any of the following methods:

- Agency Web Site: *http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- E-mail: *regs.comments@federalreserve.gov.* Include the docket number in the subject line of the message.
- FAX: (202) 452–3819 or (202) 452–3102.
- Mail: Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board's Martin Building (20th and C Streets, NW.) between 9 a.m. and 5 p.m. on weekdays.

FOR FURTHER INFORMATION CONTACT: Heatherun Sophia Allison, Senior Counsel (202/452–3565), or Kara Handzlik, Attorney (202/452–3852), Legal Division, Seth Carpenter, Assistant Director and Section Chief (202/452–2385), or Margaret Gillis DeBoer, Financial Analyst (202/452–3139), Division of Monetary Affairs; for users of Telecommunications Device for the Deaf (TDD) only, contact (202/263–4869); Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 19 of the Federal Reserve Act (the ''Act'') imposes reserve requirements for monetary policy purposes only on certain types of deposits and other liabilities of depository institutions. Section 19 also authorizes the Board to define by regulation the terms used in the section. Currently, reserve requirement ratios for ''transaction accounts'' (accounts used to make payments to third parties, such as checking accounts) are graduated between three and ten percent. Reserve requirement ratios for ''nonpersonal time deposits'' and ''Eurocurrency liabilities'' are currently zero percent. Although Section 19 expressly defines accounts with certain transfer characteristics as ''transaction accounts,'' Section 19 also authorizes the Board ''to determine, by regulation or order, that an account or deposit is a transaction account if such account or deposit may be used to provide funds directly or indirectly for the purpose of making payments or transfers to third persons or others.'' [1] The provisions of Section 19 are implemented by the Board's Regulation D.

Section 11(a)(2) of the Act authorizes the Board to require any depository institution ''to make, at such intervals as the Board may prescribe, such reports of its liabilities and assets as the Board may determine to be necessary or desirable to enable the Board to discharge its responsibility to monitor and control monetary and credit aggregates.'' [2] These provisions are specifically implemented in the computation and maintenance provisions of Regulation D (12 CFR 204.3).

II. Pass-Through Accounts

Section 19(c)(1) of the Act provides that depository institutions shall maintain required reserves in the form of a balance maintained for such purposes by a depository institution in an account at a Federal Reserve Bank or in the form of vault cash. Prior to 2006, Section 19(c)(1)(B) of the Act provided that non-member banks could maintain required reserves in an account at a depository institution that itself maintained required reserve balances at a Federal Reserve Bank, known as a ''pass-through account.'' The Financial Services Regulatory Relief Act of 2006, Public Law 109–351 (Oct. 13, 2006), amended Section 19(c)(1)(B) of the Act to remove the language restricting pass-through arrangements to non-member banks. Accordingly, all depository institutions may if they choose maintain required reserves in a pass-through

[1] Section 19(b)(1)(F) of the Federal Reserve Act, 12 U.S.C. 461(b)(1)(F).

[2] 12 U.S.C. 248(a).

account with a correspondent depository institution.

To implement the pass-through provisions of the Financial Services Regulatory Relief Act of 2006, the Board proposes to amend the definition of ''pass-through account'' in § 204.2(*l*) and the rules for pass-through arrangements in § 204.3(i) to remove references limiting such arrangements to non-member banks.

III. Transfers From Savings Deposits

A. Six-Three Distinction

The Board has established the criteria for distinguishing between ''transaction accounts'' and ''savings deposits'' [3] in Regulation D based on the ease with which the depositor may make transfers (payments to third parties) or withdrawals (payments directly to the depositor) from the account. Generally speaking, the more convenient it is to make withdrawals or transfers from an account, the more likely it is that the account will be used for making payments or transfers to third parties as opposed to holding savings. Accordingly, Regulation D limits the number of certain convenient kinds of transfers or withdrawals that may be made in a single month from an account if that account is to be classified as a ''savings deposit.'' [4] ''Convenient'' transfers or withdrawals for this purpose include preauthorized or automatic transfers (such as overdraft protection transfers or arranging to have bill payments deducted directly from the depositor's savings account), telephonic transfers (made by the depositor telephoning or sending a fax or online instruction to the bank and instructing the transfer to be made), and transfers by check, debit card, or similar order payable to third parties.

Regulation D currently limits the number of ''convenient'' transfers and withdrawals from savings deposits (*i.e.*, preauthorized, automatic, or telephonic transfers or withdrawals) to not more than six per month. Within this overall limit of six, not more than three transfers or withdrawals may be made by check, debit card, or similar order made by the depositor and payable to third parties. Transfers and withdrawals from savings deposits that are less convenient are not limited in number by the ''savings deposit'' definition in Regulation D. For example, transfers or withdrawals made ''by mail, messenger, automated teller machine, or in person or * * * made by telephone (via check mailed to the depositor)'' may be made from savings deposits without numerical limit.

The distinction between different types of limited transfers or withdrawals from savings deposits may be referred to as the ''six-three distinction'' (*i.e.*, six convenient transfers or withdrawals, of which up to three may be by check, debit card, or similar order). The six-three distinction in the Regulation D definition of ''savings deposit'' is derived from the ''money market deposit account'' or ''MMDA'' created by the Garn-St.Germain Depository Institutions Act of 1982 (the ''1982 Act''). In the 1982 Act, Congress sought to create an account to meet the perceived market need for an interest-bearing deposit account that was both directly competitive with money market mutual funds and not the functional equivalent of a reservable transaction account. The definition of ''transaction account'' in Regulation D at that time included any account from which more than three preauthorized, automatic or telephonic transfers or withdrawals per month were permitted. Congress therefore specified in the 1982 Act that the MMDA was not to be considered a ''transaction account'' (and, therefore, not subject to reserve requirements) even though it permitted ''three preauthorized or automatic transfers and three third-party transfers'' per month.

The legislative history of the 1982 Act did not clarify whether this authorization was intended to allow ''three preauthorized or automatic transfers'' and a separate set of ''three third-party transfers.'' It simply noted that ''third-party transfers'' were intended to include checks. The existing provisions of Regulation D, however, considered ''preauthorized or automatic'' transfers to include transfers to third parties as well. To harmonize the legislative history of the 1982 Act with the existing provisions of Regulation D, the MMDA was regulatorily defined to permit a depositor who did not write any checks in a particular month to make up to six preauthorized or automatic transfers per month. In no event, however, would more than three checks per month be permitted.

In 1986, the statutory provisions that authorized the MMDA and that exempted the MMDA from the ''transaction account'' definition expired. In subsequent rulemakings, however, the Board preserved the transfer and withdrawal characteristics of the MMDA in Regulation D by merging the definition of ''MMDA'' into the definition of ''savings deposit.'' Thus, any deposit that permitted up to six preauthorized, automatic, or telephonic transfers or withdrawals, including not more than three transfers made by check, debit card, or similar third-party order, was classified under Regulation D as a ''savings deposit.''

B. Proposed Amendment Eliminating ''Three'' Limit

Depository institutions have identified the six-three distinction in Regulation D as a regulatory burden in various contexts, as distinctions that have historically been drawn between ''six'' or ''three'' transfers or withdrawals are overtaken by developments in payments technology. In light of the foregoing, the Board believes it would now be appropriate to amend Regulation D to do away with the sublimit of three that applies to checks and drafts and simply limit all ''convenient'' transfers to not more than six per month.[5] Eliminating the ''six-three distinction'' and replacing it with a simpler ''six-per-month'' rule for all types of ''convenient'' transfers or withdrawals from savings deposits would reduce some aspects of the current limitations that are burdensome to the private sector and that may interfere with the broader use and acceptance of developing electronic payments technologies.

A ''six-per-month'' rule could result in a slight decrease in aggregate transaction account balances, as those accounts that permit more than three but less than six transfers by check or debit card per month would shift from their current classification as ''transaction accounts'' to ''savings deposits.'' The extent of such a decrease, if any, is difficult to predict given the lack of data on the distribution of frequency of withdrawals and transfers from various accounts. The net effects, however, seem unlikely to be large.

IV. Other Proposed Amendments

A. Harmonization With Existing Usage or Staff Guidance

Certain proposed amendments would amend definitions of existing terms to harmonize them with existing usage, practice, or staff guidance. For example,

[3] The Board has by regulation included ''savings deposits'' held by nonnatural persons (*i.e.*, anyone other than individuals) in the Regulation D definition of ''nonpersonal time deposits.'' Accordingly, such deposits are subject to a zero percent reserve requirement. Savings deposits held by natural persons (individuals), on the other hand, are not subject to reserve requirements at all. As a practical matter, therefore, ''savings deposits'' of all kinds are not reservable; the distinction between personal and nonpersonal savings deposits is significant for deposit reporting purposes only.

[4] 12 CFR 204.2(d)(2) (definition of ''savings deposit'').

[5] 12 CFR 204.2(d)(2) (definition of ''savings deposit'').

the proposed amendments would add new provisions to the definition of ''vault cash'' in § 204.2(k) in order to incorporate the substance of numerous staff opinions that explain the circumstances under which vault cash held at ATMs and in other arrangements can qualify as ''vault cash'' for purposes of meeting reserve requirements. Also, the proposed amendments would also clarify the definition of ''time deposit'' in § 204.2(c) to incorporate staff guidance that has been issued over the years in response to numerous inquiries about the meaning of ''additional'' early withdrawal penalties and when such penalties must be imposed.

B. Reorganization of Reporting, Computation, and Maintenance Provisions

The remaining proposed amendments would reorganize the existing provisions of Regulation D relating to deposit reporting and to the computation and maintenance of required reserves. These proposed amendments would split the existing provisions on these subjects in current § 204.3 into three separate sections. First, the provisions related to submitting reports of deposits would be set forth in proposed § 204.3. Second, the provisions relating to computation of required reserves would be set forth in proposed § 204.4. Third, the provisions relating to maintenance of required reserves would be set forth in proposed § 204.5. In addition, the proposed amendments would move the reserve requirement ratio provisions of current § 204.9 into the proposed separate section relating to computation of required reserves (proposed § 204.4). Finally, the proposed amendments re-number the provisions of the regulation relating to transitional adjustments, emergency reserves, and supplemental reserves in order to reflect the creation of three separate sections out of current § 204.3.

V. Section-By-Section Analysis

Section 204.2(c)(1) Definition of ''Time Deposit''

The Board proposes to amend the definition of ''time deposit'' to clarify the application of early withdrawal penalties when there has been more than one partial early withdrawal from a time deposit. Current § 204.2(c)(1) provides that an early withdrawal penalty must be charged on any amount withdrawn from a time deposit ''from within six days after the date of deposit.'' The definition contemplates that an early withdrawal might be an early withdrawal of the entire deposit amount or of a partial withdrawal, that is, a withdrawal of some amount that is not the entire deposit amount. In either case, if part or all of the time deposit is withdrawn within six days after the date of the initial deposit, the specified early withdrawal penalty must be imposed on the amount so withdrawn.

The current definition further states that ''[a] time deposit from which partial early withdrawals are permitted must impose additional early withdrawal penalties of at least seven days' simple interest on amounts withdrawn within six days after each partial withdrawal.'' This provision has led to numerous inquiries about the meaning of the terms ''additional'' and ''early'' in this provision.[6] The Board intends to clarify that withdrawals cannot be made more frequently than every seven days from a deposit that is classified as a ''time deposit'' unless a penalty of at least seven days'' simple interest is charged on amounts so withdrawn. Accordingly, the Board proposes to amend the definition to remove the references to ''early'' and ''additional'' in the second sentence of the definition and to clarify that ''early'' withdrawals, when made other than in the first six days, are withdrawals that are within six days of the last withdrawal.

Section 204.2(d)(2) Definition of ''Savings Deposit''

As explained in III.A.–III.B., *supra,* The Board proposes to amend the definition of ''savings deposit'' to eliminate the provision limiting certain kinds of transfers from savings deposits to not more than three per month. As a result, all kinds of transfers and withdrawals from a savings deposit that must be limited in number per month would be subject to the same numeric limitation of nor more than six per month.

Section 204.2(k) Definition of ''Vault Cash''

The Board proposes to amend the definition of ''vault cash'' to incorporate the substance of prior written staff guidance on when currency and coin that is not held at a physical location of the depository institution[7] may count as ''vault cash.'' The proposed amendments divide the definition of ''vault cash'' into two subsections: one dealing with vault cash ''held at a physical location of the depository institution * * * from which the institution's depositors may make cash withdrawals;'' and the other dealing with vault cash ''held at an alternate physical location.'' The proposed amendments expand primarily the second proposed subsection to incorporate prior guidance.

From 1917 to 1959, the Act permitted member banks to satisfy reserve requirements exclusively with balances in their accounts at Federal Reserve Banks. In 1959, Congress amended Section 19 of the Act to provide that the Board, ''under such regulations as it may prescribe, may permit member banks to count all or part of their currency and coin as reserves required under this section.''[8] The 1959 legislation was intended ''to remove some generally recognized inequities that now exist in the structure of reserve requirements applicable to member banks * * *.''[9] Specifically, the legislative history recognized that currency and coin in a member bank's vault and a balance in a member bank's account at a Federal Reserve Bank were ''interchangeable'' as liabilities of the Reserve Banks.[10] For operational reasons, however, ''country banks'' generally found it necessary to hold more currency and coin in their vaults than did ''reserve city banks'' or ''central reserve city banks.''[11] Between 1959 and 1960, the Board promulgated a series of amendments to Regulation D that phased in the ability of member banks to count all of their currency and coin in satisfying reserve requirements.

In 1970, the Board issued an interpretation of Regulation D relating to the eligibility of currency or coin held principally for numismatic value to satisfy member bank reserve requirements.[12] The Board was concerned that permitting silver coin to count towards reserve requirements could encourage speculation in silver; specifically, that the banks were holding either for their own accounts with the expectation of earning a premium over face value, or were holding under written or oral agreements with specific customers whereby the customers retained the right to or an option on

[6] *E.g.,* whether two penalties (an ''early withdrawal penalty'' and an ''additional early withdrawal penalty'') must be charged on any partial early withdrawal; whether one penalty must be charged on a partial early withdrawal within the first six days of the deposit but two must be charged on subsequent partial early withdrawals; the meaning of ''early withdrawal'' as applied to a partial withdrawal made some time other than within the first six days, etc.

[7] *See, e.g.,* See FRRS ¶ 2–307.2 (rented vault); Staff Opinion of Aug. 9, 1982 (ATMs).

[8] Act of July 28, 1959 (73 Stat. 263).

[9] S. Rep. No. 86–195, at 1 (1959); H. Rep. No. 86–403, at 3 (1959).

[10] S. Rep. No. 86–195, at 3 (1959); H. Rep. No. 86–403, at 3 (1959).

[11] S. Rep. No. 86–195, at 3 (1959); H. Rep. No. 86–403, at 3 (1959).

[12] Former 12 CFR 204.116 (1979).

those coins.[13] Accordingly, the Board specified in the 1970 interpretation that in order for a member bank to count currency or coin towards reserve requirements, the member bank must have ''the full and unrestricted right to use [such currency or coin] at any time to meet depositors' claims * * *.'' [14] The 1970 interpretation also specified that a bank does not have such a ''full and unrestricted right'' if the bank is prevented, legally or practically * * * from using the currency or coin at any time to meet customer's demands.'' [15] The 1970 interpretation further specified that when assessing arrangements with respect to such currency and coin, ''[a]n agreement between the bank and its customer that the currency or coin is to be regarded as 'owned' by the bank for purposes of reserve requirements is not determinative. Whether currency or coin may be counted as reserves depends on the underlying nature of the transaction * * *.'' [16]

The 1980 Regulation D amendments implementing the Monetary Control Act of 1980 introduced the term ''vault cash'' as a defined term. The 1980 amendments defined ''vault cash'' to mean ''currency and coin owned and held by a depository institution that may, at any time, be used to satisfy depositors' claims,'' incorporating into the new definition the principles of bank ownership and availability at any time to satisfy depositors' claims from the 1970 interpretation. Subsequent Board guidance and staff opinions provided additional clarification of these requirements.

For example, vault cash ''owned and held'' by the depository institution was further clarified to include the requirements that (A) the depository institution claiming the currency or coin in question as ''vault cash'' must book the currency or coin as an asset,[17] and that (B) no other institution may claim the currency and coin towards satisfying its reserve requirements.[18] The ability to use vault cash ''at any time * * * to satisfy depositor's claims'' was initially viewed as requiring the currency or coin to be ''immediately'' available for that purpose to the bank or a branch of the bank.[19] For currency and coin to be ''immediately available,'' subsequent staff opinions specified that it be ''reasonably nearby'' a physical location (from which depositors may make cash withdrawals) of the institution claiming the vault cash towards satisfying reserve requirements.[20] To be ''reasonably nearby,'' in turn, staff believed that a depository institution customer who demanded cash at the beginning of a banking day should be able to receive that cash in satisfaction of his or her demand before the close of business on the same calendar day. Accordingly, staff opined that a depository institution must be able to recall the currency and coin in question from the remote location by not later than 4 p.m. if the recall is requested by 10 a.m. on the same calendar day for the currency and coin to constitute ''vault cash.'' Staff guidance further clarified that depository institutions must establish the ability to recall ''vault cash'' within the specified time frame by having in place a written cash delivery plan (together with written contractual arrangements necessary to implement the plan) that permits recall of the ''vault cash'' to the depository institution relying solely on ground transportation.

The proposed amendments would incorporate all of the foregoing clarifications and requirements into six new subsections applicable to ''vault cash'' held ''at an alternate physical location'' of the depository institution claiming the currency or coin in question towards satisfying its reserve requirements.[21] Finally, the proposed amendments re-number current § 204.2(k)(2)–(3) to 204.2(k)(3)–(4), to take into account the new proposed §§ 204.2(k)(1)–(2). The substance of those provisions, however, is unchanged by the proposed amendments.

Section 204.2(l) Definition of ''Pass-through Account''

The Board proposes to amend the definition of ''pass-through account'' to eliminate the language restricting pass-through account arrangements to non-member banks. The proposed amendments would also move the provisions relating to pass-through accounts currently set forth in § 204.3(i) to a new § 204.5(d), ''Maintenance of Required Reserves,'' discussed *infra.*

Section 204.2(v) Definition of ''Clearing Balance Allowance''

The proposed amendments would add a new definition of ''clearing balance allowance'' to Regulation D. The term replaces the undefined term ''required charge-free band'' that appears twice in current § 204.3(h) (concerning carryovers of excess reserves or deficiencies in reserves) because that term is no longer used in current practice. The proposed amendments would also move the existing carryover provisions in current § 204.3(h) to a new paragraph (e) under proposed § 204.5, ''Maintenance of Required Reserves,'' discussed *infra.*

Section 204.2(w) Definition of ''Contractual Clearing Balance''

The proposed amendments would add a new definition of ''contractual clearing balance'' to Regulation D. The term replaces the undefined term ''required clearing balance'' in current § 204.3(h) because the term ''contractual clearing balance'' is more commonly used and more accurately describes the relationship created thereby.

Section 204.3 Reporting and Location

Current § 204.3 of Regulation D sets forth the regulatory provisions governing the calculation of required reserves, the maintenance of required reserves, and the submission of reports of deposits (from which required reserves are calculated). The Board proposes to re-organize these provisions into three separate subsections that address these issues in their chronological order: the submission of reports of deposits, the calculation of required reserves based on those reports of deposits, and the subsequent maintenance of required reserves based on the calculation of required reserves. The proposed amendments are not intended to make substantive changes to these provisions, but rather are intended to re-organize them for greater ease of reference and to make minor editorial changes for clarity.

The first of the proposed three new paragraphs, proposed § 204.3, incorporates the existing regulatory provisions relating to submission of reports of deposits, including provisions on determining the location of the reporting institution for deposit reporting and reserves maintenance purposes.[22] The proposed amendments would also include in this paragraph

[13] 35 FR 18957 (Dec. 15, 1970).

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *See, e.g.*, F.R.R.S. ¶ 2–306.9; Staff Op. of Aug. 9, 1982.

[18] *See, e.g.*, F.R.R.S. ¶ 2–307.2; Staff Op. of Aug. 9, 1982.

[19] *See* FRRS ¶ 2–306.9; Staff Opinion of Aug. 9, 1982.

[20] *See* FRRS ¶ 2–307.2.

[21] The proposed amendments do not include the ''legitimate business purpose'' specification from written staff guidance on vault cash held in alternate physical locations (*see, e.g.*, FRRS ¶ 2–365.2), The Board believes that full compliance with the other five specifications proposed to be incorporated into the definition should ordinarily suffice to establish the legitimacy of the arrangement. The Board requests comment on whether this specification should be included in the definition of ''vault cash.''

[22] Current subsections 204.3(a)(1) last sentence, 204.3(a)(2), and 204.3(b)(2).

regulatory provisions regarding the allocation of the low reserve tranche among related depository institutions [23] and regarding overdrafts in related transaction accounts [24] because these provisions must be applied in determining the appropriate levels of deposits to report.

Proposed § 204.3(a) consists of the text of the first sentence of current § 204.3(a)(2)(i), with two proposed amendments. The first proposed amendment would clarify the authority of the Board or a Federal Reserve Bank to require reports of deposits or any other form or statement from a depository institution relating to reserve requirements. The second proposed amendment would clarify where reports of deposits are to be submitted in light of the account location provisions of the regulation.

Proposed § 204.3(b) sets forth without change the text of the second sentence of current § 204.3(a)(2)(i).

Proposed § 204.3(c) sets forth without change the text of the third (and last) sentence of current § 204.3(a)(1).

Proposed § 204.3(d) sets forth, with one change, the text of current § 204.3(a)(3). The one change would conform the section number reference to the reserve requirement ratios that are currently set forth in § 204.9 but would be moved to proposed § 204.4(f) in the proposed amendments.

No changes are proposed to current § 204.3(e), dealing with computation of transaction accounts for deposit reporting purposes.

Proposed § 204.3(g) sets forth, with two amendments, the text of current § 204.3(b)(2). The first amendment would provide that a depository institution may be considered to be located at the location specified in the institution's articles of incorporation or as specified by the institution's primary regulator. The Board proposes this amendment in light of the fact that an institution may move its head office or primary location from that specified in its charter or organizing certificate, but that the charter or organizing certificate may not reflect that move. In such cases, the move instead may be reflected in the institution's revised articles of incorporation or otherwise as recognized by the institution's primary regulator. The second amendment would conform the internal references to §§ 204.3(b)(2)(i) and 204.3(b)(2)(ii) to §§ 204.3(g)(1) and 204.3(g)(2), respectively.

[23] Current § 204.3(a)(3).

[24] Current § 204.3(e).

Section 204.4 Computation of Required Reserves

The Board proposes to move the provisions relating to computation of required reserves from where they appear in current §§ 204.3(c), 204.3(d), and 204.3(f) to a new separate paragraph, proposed § 204.4, ''Computation of Required Reserves.'' No substantive changes are intended.

Proposed § 204.4(a) sets forth, without change, the text of current § 204.3(f)(1).

Proposed § 204.4(b) sets forth, without change, the text of current § 204.3(f)(2).

Proposed § 204.4(c) sets forth, without change, the text of current § 204.3(f)(3).

Proposed §§ 204.4(d) and 204.4(e) set forth the text of current § 204.3(c)(1) and the first sentence of § 204.3, respectively, with editorial amendments for clarity.

Proposed § 204.4(f) sets forth the text of the second sentence of current § 204.3(c)(1), with editorial amendments for clarity. Proposed § 204.4(f) also incorporates, with editorial amendments for clarity, the table of reserve requirements ratios currently set forth in § 204.9 so that all regulatory provisions relating to computation of required reserves are located in the same section.

Section 204.5 Maintenance of Required Reserves

The Board proposes to move the existing provisions regarding maintenance of required reserves, including the provisions on maintenance of required reserves pursuant to pass-through agreements, to a new § 204.5, ''Maintenance of Required Reserves.'' No substantive changes are intended.

Proposed § 204.5(a)(1) sets forth the text of current § 204.3(b)(1) with various amendments. First, the amendments would delete the reference to ''non-member institutions'' in discussing pass-through arrangements. Second, the amendments would update the language (*e.g.*, ''maintain required reserves'' rather than ''hold reserves'') for consistency with current usage. Third, the amendments would conform the numeric reference from current § 204.3(i) to proposed § 204.5(d) for the regulatory provisions on pass-through arrangements.

Proposed § 204.5(a)(2) sets forth the text of current § 204.3(i)(3)(i) with editorial amendments for clarity.

Proposed § 204.5(b)(1) sets forth the text of current § 204.3(c)(2) with editorial amendments for clarity.

Proposed § 204.5(b)(2) sets forth the text of the first and third sentences of current § 204.3(d) with editorial amendments for clarity.

Proposed § 204.5(c) sets forth the text of current § 204.3(g) with an amendment to conform the name of the Board's Regulation J (12 CFR Part 210) to the current version of the regulation.

Proposed § 204.5(d) sets forth the regulatory provisions for ''pass-through accounts'' in current § 204.3(i), dividing them into four new paragraphs, proposed §§ 204.5(d)(1) through 204.5(d)(4). Proposed § 204.5(d)(1) sets forth the text from current § 204.3(i)(1)(i) with various amendments. First, the amendments would delete the reference to ''nonmember'' depository institutions, since pass-through arrangements are no longer statutorily restricted to nonmember depository institutions. Second, the amendments would clarify that depository institutions whose required reserve balances are zero may serve as pass-through correspondents. Third, the amendments conform the internal references to section numbers and make other editorial changes for clarity.

Proposed § 204.5(d)(2) sets forth, without change, the text from current § 204.3(i)(1)(ii).

Proposed § 204.5(d)(3) sets forth the text of current § 204.3(i)(2), with an amendment to delete the obsolete reference to Reserve Bank permission for alternate account locations. Determination of account location is addressed in current § 204.3(b) (proposed § 204.3(g)).

Proposed § 204.5(d)(4) sets forth, in four new subsections, the text of current §§ 204.3(i)(3)(ii)–(v). Proposed § 204.5(d)(4)(A) sets forth the text of current § 204.3(i)(3)(ii) with an amendment deleting the reference to more than one depository institution account at a Federal Reserve Bank. Proposed §§ 204.5(d)(4)(B) and 204.5(d)(4)(C) set forth, without change, the text of current §§ 204.3(i)(3)(iii) and 204.3(i)(3)(iv), respectively. Proposed § 204.5(d)(4)(D) sets forth the text of current § 204.3(i)(3)(v) with an amendment conforming the section number reference to the supplemental reserves provisions of the regulation (current § 204.6, proposed § 204.10).

Proposed § 204.5(e) sets forth the text of current § 204.3(h), with amendments deleting obsolete references to ''required clearing balance'' and to ''required charge-free band.'' Other editorial amendments are made for clarity.

Section 204.6 Charges for Reserve Deficiencies

The Board proposes to move the existing provisions regarding charges for reserve deficiencies from current § 204.7 to proposed § 204.6 and to revise the

current caption of the section (from ''Penalties'' to ''Charges for Reserve Deficiencies''). The four proposed sections in proposed § 204.6 set forth the text of current § 204.7, deleting provisions describing guidelines for waivers by Reserve Banks of small charges. The Board believes that the deletion of this material is appropriate because it describes only in part the extent of the discretion of the Reserve Banks in this regard and to avoid the implication that Reserve Banks must waive charges in certain of the cases described.

Section 204.7 Transitional Adjustments in Mergers

The Board proposes to re-designate the provision from current § 204.4 to proposed § 204.7. No other changes to the section are proposed.

Section 204.8 International Banking Facilities

No changes are proposed to § 204.8.

Section 204.9 Emergency Reserve Requirement

The Board proposes to re-designate the provision from current § 204.5 to proposed § 204.9. No other changes to the section are proposed.

Section 204.10 Supplemental Reserve Requirement

The Board proposes to re-designate the provision from current § 204.6 to proposed § 204.10. No other changes to the section are proposed.

Regulation I Section 209.2(c)(1) Location of Bank—General Rule

The Board proposes to amend this provision of Regulation I to conform it to the proposed § 204.3(g) of Regulation D, discussed *supra*. Specifically, the amendment would provide that a depository institution may be considered to be located at the location specified in the institution's articles of incorporation or as specified by the institution's primary regulator. The Board proposes this amendment in light of the fact that an institution may move its head office or primary location from that specified in its charter or organizing certificate, but that the charter or organizing certificate may not reflect that move. In such cases, the move instead may be reflected in the institution's revised articles of incorporation or otherwise as recognized by the institution's primary regulator.

VI. Form of Comment Letters

Comment letters should refer to Docket No. R-____ and, when possible, should use a standard typeface with a font size of 10 or 12; this will enable the Board to convert text submitted in paper form to machine-readable form through electronic scanning, and will facilitate automated retrieval of comments for review. Comments may be mailed electronically to *regs.comments@federalreserve.gov*.

VII. Solicitation of Comments Regarding Use of ''Plain Language''

Section 722 of the Gramm-Leach-Bliley Act of 1999 requires the Board to use ''plain language'' in all proposed and final rules published after January 1, 2000. The Board invites comments on whether the proposed rule is clearly stated and effectively organized, and how the Board might make the proposed text easier to understand.

VIII. Initial Regulatory Flexibility Analysis

In accordance with Section 3(a) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601, *et seq.*), the Board has reviewed the proposed amendments to Regulation D and Regulation I. A final regulatory flexibility analysis will be conducted after consideration of comments received during the public comment period.

1. *Statement of the objectives of the proposal.* The Board is proposing to amend Regulation D and Regulation I in order to conform the regulation to the provisions of the Financial Services Regulatory Relief Act of 2006, to modernize the regulation in light of technological developments, to reduce regulatory burden, and to simplify regulatory compliance. Section 19 of the Act was enacted to impose reserve requirements on certain deposits and other liabilities of depository institutions for monetary policy purposes. Section 19 also authorizes the Board to promulgate such regulations as it may deem necessary to effectuate the purposes of the section. The Board believes that the proposed amendment to Regulation D is within the Congress' broad grant of authority to the Board to adopt provisions that carry out the purposes of Section 19 of the Act.

2. *Small entities affected by the proposal.* The proposal would affect all depository institutions that are currently subject to transaction account reserve requirements. The Board estimates that there are currently approximately 8,195 depository institutions that are subject to transaction account reserve requirements. The Board estimates that approximately 3,800 of these institutions could be considered small entities with assets of $165 million or less. The proposed rule, if adopted, may reduce the level of reservable transaction account balances for all depository institutions because ''savings deposits'' that previously permitted more than three but less than six ''convenient'' transfers would be classified as nonreservable ''savings deposits'' under the proposed rule, but are currently classified as reservable ''transaction accounts.''

3. *Other federal rules.* The Board believes that no federal rules duplicate, overlap, or conflict with the proposed revisions to the Interpretation.

4. *Significant alternatives to the proposed revisions.* The Board welcomes comment on any significant alternatives that would minimize the impact of the proposed rule on small entities.

IX. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3506; 5 CFR part 1320 Appendix A.1), the Board reviewed the proposed rule under the authority delegated to the Board by the Office of Management and Budget (OMB). The proposed rule contains no requirements subject to the PRA.

Test of Proposed Revisions

Certain conventions have been used to highlight the proposed revisions. New language is shown inside arrows while language that would be deleted is set off with brackets.

List of Subjects in 12 CFR Parts 204 and 209

Banks, Banking, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Board proposes to amend 12 CFR parts 204 and 209 as follows:

PART 204—RESERVE REQUIREMENTS OF DEPOSITORY INSTITUTIONS (REGULATION D)

1. The authority citation for part 204 continues to read as follows:

Authority: 12 U.S.C. 248(a), 248(c), 371a, 461, 601, 611, and 3105.

2. Section 204.2 is amended by revising paragraphs I(1)(i) introductory text, (d)(2), (k) and (l), and adding new paragraphs (v) and (w) to read as follows:

§ 204.2 Definitions.

* * * * *

(c) * * *

(1) * * *

(i) A deposit [that] ►from which◄ the depositor does not have a right and is not permitted to make withdrawals [from] within six days after the date of

deposit unless the deposit is subject to an early withdrawal penalty of at least seven days' simple interest on amounts withdrawn within the first six days after deposit.[1] A time deposit from which partial [early] withdrawals are permitted ►within six days after the date of the last withdrawal◄ must impose [additional] early withdrawal penalties of at least seven days' simple interest on amounts ►so◄ withdrawn [within six days after each partial withdrawal]. If [such additional] early withdrawal penalties are not imposed, the account ceases to be a time deposit. The account may become a savings deposit if it meets the requirements for a saving deposit; otherwise it becomes a transaction account. Time deposit includes funds—

* * * * *

(d) * * *

(2) The term savings deposit also means: A deposit or account, such as an account commonly known as a passbook savings account, a statement savings account, or as a money market deposit account (MMDA), that otherwise meets the requirements of § 204.2(d)(1) and from which, under the terms of the deposit contract or by practice of the depository institution, the depositor is permitted or authorized to make no more than six transfers and withdrawals, or a combination of such transfers and withdrawals, per calendar month or statement cycle (or similar period) of at least four weeks, to another account (including a transaction account) of the depositor at the same institution or to a third party by means of a preauthorized or automatic transfer, or telephonic (including data transmission) agreement, order or instruction, [and no more than three of the six such transfers may be made] ►or◄ by check, draft, debit card, or similar order made by the depositor and payable to third parties. A preauthorized transfer includes any arrangement by the depository institution to pay a third party from the account of a depositor upon written or oral instruction (including an order received through an automated clearing house (ACH)) or any arrangement by a depository institution to pay a third party from the account of the depositor at a predetermined time or on a fixed schedule. Such an account is not a transaction account by virtue of an arrangement that permits transfers for the purpose of repaying loans and associated expenses at the same depository institution (as originator or servicer) or that permits transfers of funds from this account to another account of the same depositor at the same institution or permits withdrawals (payments directly to the depositor) from the account when such transfers or withdrawals are made by mail, messenger, automated teller machine, or in person or when such withdrawals are made by telephone (via check mailed to the depositor) regardless of the number of such transfers or withdrawals.[4]

* * * * *

(k)(1) *Vault cash* means United States currency and coin owned and [held] ►booked as an asset◄ by a depository institution that may, at any time, be used to satisfy [depositors'] claims ►of that depository institution's depositors and that meets the requirements of paragraph (k)(2)(i) or (k)(2)(ii) of this section◄.

(2) *Vault cash* ►must be either:

(i) Held at a physical location of the depository institution (including the depository institution's proprietary ATMs) from which the institution's depositors may make cash withdrawals; or

(ii) Held at an alternate physical location if—

(A) The depository institution claiming the currency and coin as vault cash at all times retains full rights of ownership in and to the currency and coin held at the alternate physical location;

(B) The depository institution claiming the currency and coin as vault cash at all times books the currency and coin held at the alternate physical location as an asset of the depository institution;

(C) No other depository institution claims the currency and coin held at the alternate physical location as vault cash in satisfaction of that other depository institution's reserve requirements;

(D) The currency and coin held at the alternate physical location is reasonably nearby a location of the depository institution claiming the currency and coin as vault cash at which its depositors may make cash withdrawals (an alternate physical location is considered ''reasonably nearby'' if the depository institution that claims the currency and coin as vault cash can recall the currency and coin from the alternate physical location by 10 a.m. and, relying solely on ground transportation, receive the currency and coin not later than 4 p.m. on the same calendar day at a location of the depository institution at which its depositors may make cash withdrawals); and

(E) The depository institution claiming the currency and coin as vault cash has in place a written cash delivery plan, and written contractual arrangements necessary to implement that plan, that demonstrate that the currency and coin can be recalled and received in accordance with the requirements of paragraph (k)(2)(ii)(D) of this section at any time. The depository institution shall provide copies of the written cash delivery plan and written contractual arrangements to the Federal Reserve Bank that holds its account or to the Board upon request.

(3) Vault cash◄ includes United States currency and coin in transit to a

[1] A time deposit, or a portion thereof, may be paid during the period when an early withdrawal penalty would otherwise be required under this part without imposing an early withdrawal penalty specified by this part:

(a) Where the time deposit is maintained in an individual retirement account established in accordance with 26 U.S.C. 408 and is paid within seven days after establishment of the individual retirement account pursuant to 26 CFR 1.408–6(d)(4), where it is maintained in a Keogh (H.R. 10) plan, or where it is maintained in a *401(k) plan* under 26 U.S.C. 401(k); *Provided* that the depositor forfeits an amount at least equal to the simple interest earned on the amount withdrawn;

(b) Where the depository institution pays all or a portion of a time deposit representing funds contributed to an individual retirement account or a Keogh (H.R. 10) plan established pursuant to 26 U.S.C. 408 or 26 U.S.C. 401 or to a *401(k) plan* established pursuant to 26 U.S.C. 401(k) when the individual for whose benefit the account is maintained attains age 59½ or is disabled (as defined in 26 U.S.C. 72(m)(7)) or thereafter;

(c) Where the depository institution pays that portion of a time deposit on which federal deposit insurance has been lost as a result of the merger of two or more federally insured banks in which the depositor previously maintained separate time deposits, for a period of one year from the date of the merger;

(d) Upon the death of any owner of the time deposit funds;

(e) When any owner of the time deposit is determined to be legally incompetent by a court or other administrative body of competent jurisdiction; or

(f) Where a time deposit is withdrawn within 10 days after a specified maturity date even though the deposit contract provided for automatic renewal at the maturity date.

[4] In order to ensure that no more than the permitted number of withdrawals or transfers are made, for an account to come within the [definitions in paragraph (d)(2) of this section,] ►definition of ''savings deposit,''◄ a depository institution must either:

(a) Prevent withdrawals or transfers of funds from this account that are in excess of the limits established by paragraph (d)(2) of this section, or

(b) Adopt procedures to monitor those transfers on an ex post basis and contact customers who exceed the established limits on more than occasional basis. For customers who continue to violate those limits after they have been contacted by the depository institution, the depository institution must either close the account and place the funds in another account that the depositor is eligible to maintain or take away the transfer and draft capacities of the account. An account that authorizes withdrawals or transfers in excess of the permitted number is a transaction account regardless of whether the authorized number of transactions are actually made. For accounts described in paragraph (d)(2) of this section, the institution at its option may use, on a consistent basis, either the date on the check, draft, or similar item, or the date the item is paid in applying the limits imposed by that section.

Federal Reserve Bank or a correspondent depository institution for which the reporting depository institution has not yet received credit, and United States currency and coin in transit from a Federal Reserve Bank or a correspondent depository institution when the reporting depository institution's account at the Federal Reserve or correspondent bank has been charged for such shipment.

[(3)] ►(4)◄ Silver and gold coin and other currency and coin whose numismatic or bullion value is substantially in excess of face value is not vault cash for purposes of this part.

(l) *Pass-through account* means a balance maintained by a depository institution ►with a correspondent institution under § 204.5(d)◄ [a balance maintained by a depository institution that is not a member bank, by a U.S. branch or agency of a foreign bank, or by an Edge or Agreement Corporation, (1) in an institution that maintains required reserve balances at a Federal Reserve Bank, (2) in a Federal Home Loan Bank, (3) in the National Credit Union Administration Central Liquidity Facility, or (4) in an institution that has been authorized by the Board to pass through required reserve balances if the institution, Federal Home Loan Bank, or National Credit Union Administration Central Liquidity Facility maintains the funds in the form of a balance in a Federal Reserve Bank of which it is a member or at which it maintains an account in accordance with rules and regulations of the Board].

* * * * *

►(v) Clearing balance allowance means the greater of $25,000 or two percent of an institution's contractual clearing balance.

(w) Contractual clearing balance means an amount that a depository institution agrees or is required to maintain in its account at a Federal Reserve Bank in addition to balances the depository institution may hold to satisfy its required reserve balance. A depository institution that has a required reserve balance of zero may still hold a contractual clearing balance.◄

3. Amend § 204.3 by revising the heading and paragraphs (a) through (d), (f), and (g) to read as follows:

§ 204.3 Reporting and location.

(a) Every depository institution, U.S. branch or agency of a foreign bank, and Edge or Agreement corporation shall file a report of deposits (or any other form or statement that may be required by the Board or by a Federal Reserve Bank) with the Federal Reserve Bank in the Federal Reserve District in which it is located, regardless of the manner in which it chooses to maintain required reserve balances.

(b) A foreign bank's U.S. branches and agencies and an Edge or Agreement corporation's offices operating within the same state and the same Federal Reserve District shall prepare and file a report of deposits on an aggregated basis.

(c) For purposes of this part, the obligations of a majority-owned (50 percent or more) U.S. subsidiary (except an Edge or agreement corporation) of a depository institution shall be regarded as obligations of the parent depository institution.

(d) A depository institution, a foreign bank, or an Edge or Agreement corporation shall, if possible, assign the low reserve tranche and reserve requirement exemption prescribed in § 204.4(f) to only one office or to a group of offices filing a single aggregated report of deposits. The amount of the reserve requirement exemption allocated to an office or group of offices may not exceed the amount of the low reserve tranche allocated to such office or offices. If the low reserve tranche or reserve requirement exemption cannot be fully utilized by a single office or by a group of offices filing a single report of deposits, the unused portion of the tranche or exemption may be assigned to other offices or groups of offices of the same institution until the amount of the tranche (or net transaction accounts) or exemption (or reservable liabilities) is exhausted. The tranche or exemption may be reallocated each year concurrent with implementation of the indexed tranche and exemption, or, if necessary during the course of the year to avoid underutilization of the tranche or exemption, at the beginning of a reserve computation period.◄

* * * * *

►(f) The Board and the Federal Reserve Banks will not hold a pass-through correspondent responsible for guaranteeing the accuracy of the reports of deposits submitted by its respondents.

(g)(1) For purposes of this section, a depository institution, a U.S. branch or agency of a foreign bank, or an Edge or Agreement corporation is located in the Federal Reserve District that contains the location specified in the institution's charter, organizing certificate, license, or articles of incorporation, or as specified by the institution's primary regulator, or if no such location is specified, the location of its head office, unless otherwise determined by the Board under paragraph (g)(2) of this section.

(2) If the location specified in paragraph (g)(1) of this section, in the Board's judgment, is ambiguous, would impede the ability of the Board or the Federal Reserve Banks to perform their functions under the Federal Reserve Act, or would impede the ability of the institution to operate efficiently, the Board will determine the Federal Reserve District in which the institution is located, after consultation with the institution and the relevant Federal Reserve Banks. The relevant Federal Reserve Banks are the Federal Reserve Bank whose District contains the location specified in paragraph (g)(1) of this section and the Federal Reserve Bank in whose District the institution is proposed to be located. In making this determination, the Board will consider any applicable laws, the business needs of the institution, the location of the institution's head office, the locations where the institution performs its business, and the locations that would allow the institution, the Board, and the Federal Reserve Banks to perform their functions efficiently and effectively.◄

* * * * *

4. Section 204.7 is removed, § 204.4 is redesignated as § 204.7, and a new § 204.4 is added to read as follows:

§ 204.4 Computation of required reserves.

(a) In determining the reserve balance required under this part, the amount of cash items in process of collection and balances subject to immediate withdrawal due from other depository institutions located in the United States (including such amounts due from United States branches and agencies of foreign banks and Edge and agreement corporations) may be deducted from the amount of gross transaction accounts. The amount that may be deducted may not exceed the amount of gross transaction accounts.

(b) United States branches and agencies of a foreign bank may not deduct balances due from another United States branch or agency of the same foreign bank, and United States offices of an Edge or Agreement Corporation may not deduct balances due from another United States office of the same Edge Corporation.

(c) Balances ''due from other depository institutions'' do not include balances due from Federal Reserve Banks, pass-through accounts, or balances (payable in dollars or otherwise) due from banking offices located outside the United States. An institution exercising fiduciary powers may not include in balances ''due from other depository institutions'' amounts of trust funds deposited with other

banks and due to it as a trustee or other fiduciary.

(d) For institutions that file a report of deposits weekly, required reserves are computed on the basis of the institution's daily average balances of deposits and Eurocurrency liabilities during a 14-day computation period ending every second Monday.

(e) For institutions that file a report of deposits quarterly, required reserves are computed on the basis of the institution's daily average balances of deposits and Eurocurrency liabilities during the 7-day computation period that begins on the third Tuesday of March, June, September, and December.

(f) For all depository institutions, Edge and agreement corporations, and United States branches and agencies of foreign banks, required reserves are computed by applying the reserve requirement ratios below to net transaction accounts, nonpersonal time deposits, and Eurocurrency liabilities of the institution during the computation period.

Reservable liability	Reserve requirement ratio
NET TRANSACTION ACCOUNTS:	
$0 to reserve requirement exemption amount ($9.3 million)	0 percent of amount.
Over reserve requirement exemption amount ($9.3 million) and up to low reserve tranche ($43.9 million).	3 percent of amount.
Over low reserve tranche ($43.9 million)	$1,038,000 plus 10 percent of amount over $43.9 million.
Nonpersonal time deposits	0 percent.
Eurocurrency liabilities	0 percent.

5. Section 204.9 is removed, § 204.5 is redesignated as § 204.9, and a new § 204.5 is added to read as follows:

§ 204.5 Maintenance of required reserves.

(a)(1) A depository institution, a U.S. branch or agency of a foreign bank, and an Edge or agreement corporation shall maintain required reserves in the form of vault cash and, if vault cash does not fully satisfy the institution's required reserves, in the form of a balance maintained

(i) directly with the Federal Reserve Bank in the Federal Reserve District in which the institution is located, or

(ii) with a pass-through correspondent in accordance with § 204.5(d).

(2) Each individual institution subject to this part is responsible for satisfying its required reserve balance, if any, either directly with a Federal Reserve Bank or through a pass-through correspondent.

(b)(1) For institutions that file a report of deposits weekly, the balances that are required to be maintained with the Federal Reserve shall be maintained during a 14-day maintenance period that begins on the third Thursday following the end of a given computation period.

(2) For institutions that file a report of deposits quarterly, the balances that are required to be maintained with the Federal Reserve shall be maintained during each of the 7-day maintenance periods during the interval that begins on the fourth Thursday following the end of the institution's computation period and ends on the fourth Wednesday after the close of the institution's next computation period.

(c) Cash items forwarded to a Federal Reserve Bank for collection and credit shall not be counted as part of the reserve balance to be carried with the Federal Reserve until the expiration of the time specified in the appropriate time schedule established under Regulation J, ''Collection of Checks and Other Items by Federal Reserve Banks and Funds Transfers Through Fedwire'' (12 CFR Part 210). If a depository institution draws against items before that time, the charge will be made to its account if the balance is sufficient to pay it; any resulting impairment of reserve balances will be subject to the penalties provided by law and to the reserve-deficiency charges provided by this part. However, the Federal Reserve Bank may, at its discretion, refuse to permit the withdrawal or other use of credit given in an account for any time for which the Federal Reserve Bank has not received payment in actually and finally collected funds.

(d)(1) A depository institution, a U.S. branch or agency of a foreign bank, or an Edge or Agreement corporation required to maintain reserve balances (''respondent'') may select only one pass-through correspondent institution to pass through its required reserve balances, unless otherwise permitted by Federal Reserve Bank in whose District the respondent is located. Eligible pass-through correspondent institutions are Federal Home Loan Banks, the National Credit Union Administration Central Liquidity Facility, and depository institutions, U.S. branches or agencies of foreign banks, and Edge and Agreement corporations that maintain required reserve balances, which may be zero, at a Federal Reserve Bank. In addition, the Board reserves the right to permit other institutions, on a case-by-case basis, to serve as pass-through correspondents. The correspondent chosen must subsequently pass through the required reserve balances of its respondents directly to a Federal Reserve Bank. The correspondent placing funds with a Federal Reserve Bank on behalf of respondents will be responsible for account maintenance as described in paragraph (d)(4) of this section.

(2) Respondents or correspondents may institute, terminate, or change pass-through agreements for the maintenance of required reserve balances by providing all documentation required for the establishment of the new agreement or termination of the existing agreement to the Federal Reserve Banks involved within the time period provided for such a change by those Reserve Banks.

(3) A correspondent that passes through required reserve balances of respondents shall maintain such balances, along with the correspondent's own required reserve balances (if any), in a single commingled account at the Federal Reserve Bank in whose District the correspondent is located. The balances held by the correspondent in an account at a Reserve Bank are the property of the correspondent and represent a liability of the Reserve Bank solely to the correspondent, regardless of whether the funds represent the reserve balances of another institution that have been passed through the correspondent.

(4)(i) A pass-through correspondent shall be responsible for assuring the maintenance of the appropriate aggregate level of its respondents' required reserve balances. A Federal Reserve Bank will compare the total reserve balance required to be maintained with the total actual reserve

balance held in such account for purposes of determining required-reserve deficiencies, imposing or waiving charges for deficiencies in required reserves, and for other reserve maintenance purposes. A charge for a deficiency in the aggregate level of the required reserve balance will be imposed by the Reserve Bank on the correspondent maintaining the account.

(ii) Each correspondent is required to maintain detailed records for each of its respondents in a manner that permits Reserve Banks to determine whether the respondent has provided a sufficient required reserve balance to the correspondent. A correspondent passing through a respondent's required reserve balance shall maintain records and make such reports as the Board or Reserve Bank requires in order to ensure the correspondent's compliance with its responsibilities for the maintenance of a respondent's reserve balance. Such records shall be available to the Reserve Banks as required.

(iii) The Federal Reserve Bank may terminate any pass-through agreement under which the correspondent is deficient in its recordkeeping or other responsibilities.

(iv) Interest paid on supplemental reserves (if such reserves are required under § 204.10) held by a respondent will be credited to the account maintained by the correspondent.

(e) Any excess or deficiency in an institution's required reserve balance shall be carried over and applied against the balance maintained in the next maintenance period as specified in this paragraph. The amount of any such excess or deficiency that is carried over shall not exceed the greater of:

(1) The amount obtained by multiplying .04 times the sum of depository institution's required reserves and the depository institution's contractual clearing balance, if any, and then subtracting from this product the depository institution's clearing balance allowance, if any; or

(2) $50,000, minus the depository institution's clearing balance allowance, if any. Any carryover not offset during the next period may not be carried over to subsequent periods.►

6. Section 204.6 is redesignated as § 204.10, and a new § 204.6 is added to read as follows:

►§ 204.6 Charges for reserve deficiencies.

(a) Deficiencies in a depository institution's required reserve balance, after application of the carryover provided in § 204.5(e) are subject reserve-deficiency charges. Federal Reserve Banks are authorized to assess charges for deficiencies in required reserves at a rate of 1 percentage point per year above the primary credit rate, as provided in § 201.51(a) of this chapter, in effect for borrowings from the Federal Reserve Bank on the first day of the calendar month in which the deficiencies occurred.—Charges shall be assessed on the basis of daily average deficiencies during each maintenance period. Reserve Banks may, as an alternative to levying monetary charges, after consideration of the circumstances involved, permit a depository institution to eliminate deficiencies in its required reserve balance by maintaining additional reserves during subsequent reserve maintenance periods.

(b) Reserve Banks may waive the charges for reserve deficiencies except when the deficiency arises out of a depository institution's gross negligence or conduct that is inconsistent with the principles and purposes of reserve requirements. If a depository institution has demonstrated a lack of due regard for the proper maintenance of required reserves, the Reserve Bank may decline to exercise the waiver privilege and assess all charges regardless of amount or reason for the deficiency.

(c) In individual cases, where a federal supervisory authority waives a liquidity requirement, or waives the penalty for failing to satisfy a liquidity requirement, the Reserve Bank in the District where the involved depository institution is located shall waive the reserve requirement imposed under this part for such depository institution when requested by the federal supervisory authority involved.

(d) Violations of this part may be subject to assessment of civil money penalties by the Board under authority of Section 19(1) of the Federal Reserve Act (12 U.S.C. 505) as implemented in 12 CFR part 263. In addition, the Board and any other Federal financial institution supervisory authority may enforce this part with respect to depository institutions subject to their jurisdiction under authority conferred by law to undertake cease and desist proceedings.◄

PART 209—ISSUE AND CANCELLATION OF FEDERAL RESERVE BANK CAPITAL STOCK (REGULATION I)

7. The authority citation for part 209 continues to read as follows:

Authority: 12 U.S.C. 2222, 248, 282, 286–288, 321, 323, 327–328, 333, and 466.

8. Section 209.2 is amended by revising paragraph (c)(1) to read as follows:

§ 209.2 Banks desiring to become member banks.

* * * * *

(c) * * *

(1) *General rule.* For purposes of this part, a national bank or a state bank is located in the Federal Reserve District that contains the location specified in the bank's charter or organizing certificate, ►or as specified by the institution's primary regulator,◄ or if no such location is specified, the location of its head office, unless otherwise determined by the Board under paragraph (c)(2) of this section.

* * * * *

By order of the Board of Governors of the Federal Reserve System, February 7, 2008.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E8–2558 Filed 2–11–08; 8:45 am]

BILLING CODE 6210–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2007–0185; FRL–8528–2]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Incorporation of On-Board Diagnostic Testing and Other Amendments to the Motor Vehicle Emission Inspection Program for the Northern Virginia Program Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve three State Implementation Plan (SIP) revisions submitted by the Commonwealth of Virginia. These revisions pertain to the Commonwealth's motor vehicle inspection and maintenance (I/M) program for the Northern Virginia area, which had previously been SIP-approved by EPA. These revisions incorporate several changes made by the Commonwealth since EPA last approved the I/M program as part of the SIP in 2002. The most significant change to the program is the incorporation of on-board diagnostic computer checks of 1996 and newer model year vehicles as an element of the emission inspection process for the Northern Virginia program area. In addition, Virginia has also made numerous minor changes to the program, including several changes to test procedures and standards, as well as changes to its roadside testing regimen. The I/M program helps to

ensure that highway motor vehicles operate as cleanly as possible, by requiring vehicles to be periodically tested and by identifying vehicles having high emissions due to malfunctioning emission control systems. Such vehicles must then be repaired and retested by their owners, to the standards set by the Commonwealth's program. Vehicle I/M programs address nitrogen oxide and volatile organic compound emissions, both of which are precursors to formation of ground level ozone pollution, as well as the pollutant carbon monoxide. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before March 13, 2008.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2007–0185 by one of the following methods:

A. *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. *E-mail: fernandez.cristina@epa.gov*.

C. *Mail:* EPA–R03–OAR–2007–0185, Cristina Fernandez, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2007–0185. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Brian Rehn, (215) 814–2176, or by e-mail at *rehn.brian@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Table of Contents

I. What Action Is EPA Proposing To Take?

On December 18, 2002, the Commonwealth of Virginia formally submitted a revision to its prior approved enhanced I/M program SIP for the Northern Virginia inspection and maintenance program. On April 2, 2003, the Virginia Department of Environmental Quality (VA DEQ) submitted a SIP technical amendment to the December 18, 2002 SIP revision. On June 18, 2007, VA DEQ submitted another SIP revision, which contained updated I/M program regulations made since the time of the last SIP submittal.

The Northern Virginia I/M program area is comprised of the following localities: the counties of Arlington, Fairfax, Loudoun, Prince William, and Stafford; and the cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park. It is designated by EPA as a moderate 8-hour ozone nonattainment area. The Commonwealth's revised program satisfies federal requirements under sections 182 and 184 of the Clean Air Act applicable to enhanced I/M programs, and EPA is, therefore, proposing to approve the Commonwealth's revisions to the SIP approved I/M program.

II. Background

On December 18, 2002, the VA DEQ submitted a formal request to EPA to revise the Commonwealth's SIP in relation to its motor vehicle enhanced I/M program. The Commonwealth later submitted two other SIP revisions related to the enhanced I/M program—on April 2, 2003 and on June 18, 2007. These latest revisions serve to amend the Commonwealth's prior, EPA-approved enhanced I/M SIP, which was published as a final rulemaking action in the September 1, 1999 edition of the **Federal Register** (64 FR 47670).

The Commonwealth's December 18, 2002 SIP revision consists of a revised emissions inspection program regulation published in the June 17, 2002 edition of the *Virginia Register of Regulations* (Volume 18, Issue 20), which amended a 1999 version of that regulation. Virginia's regulation, codified at Title 9, Chapter 91 of the Virginia Administrative Code (VAC), is entitled ''Regulations for the Control of Motor Vehicle Emissions in the Northern Virginia Area,'' but is also referred to here as the Virginia I/M regulation. The Commonwealth amended its emissions inspection program regulations to reflect technical changes that Virginia DEQ deemed necessary for continued program operation since the inception of its enhanced emission inspection program. Some of these regulatory amendments were made by Virginia to reflect changing federal requirements and policies that apply to enhanced emission inspection programs, and some updates were to address changes made to relevant Virginia law since the inception of the enhanced I/M program.

The most significant of the changes comprised within the December 18, 2002 SIP revision is the incorporation of on-board diagnostic checks of 1996 and newer vehicles subject to emissions testing. Virginia also updated its testing procedures to stay abreast of changes

needed based upon past operation of the program, and modified applicability of the program to address the changing dynamic of the vehicle fleet operating in the program area. Finally, Virginia also amended its regulation to enhance the Commonwealth's ability to effectively enforce the emission inspection program.

Virginia later submitted a SIP revision on April 2, 2003, which makes a technical correction to the emission inspection program regulation for Northern Virginia. This latter amendment corrects a technical error in Virginia's prior emission inspection program regulation concerning emission inspector identification numbers.

Virginia's June 18, 2007 SIP revision contains newer regulatory amendments made by Virginia since the June 2002 version of the regulation contained in the December 18, 2002 SIP revision.

The June 18, 2007 SIP revision revised provisions related to on-road testing of vehicles (i.e., remote sensing) operating primarily in Northern Virginia to ensure motorist compliance and to supplement State enforcement activities.

EPA is taking a single rulemaking action today upon the December 18, 2002, the April 2, 2003, and the June 18, 2007 SIP revisions.

III. Summary of the Commonwealth's SIP Revisions

A. Virginia's December 18, 2002 SIP Revision

In 2002, Virginia issued a final rule revising the inspection and maintenance of motor vehicles. This revised regulation was published in the June 17, 2002 edition of the *Virginia Register of Regulations* (Volume 18, Issue 20), and was submitted to EPA as part of the December 18, 2002 SIP revision. The program was revised to update the regulations to reflect changes made in the operation of emissions testing in Virginia since the last major update of the I/M regulation in 1999. The regulation was also changed to reflect changes in Federal requirements applicable to I/M programs since the enhanced I/M program was SIP-approved by EPA. The program was also amended to reflect changes in Virginia law relevant to the I/M program since the inception of the enhanced I/M program.

Among the most significant of the Commonwealth's regulatory amendments was the incorporation and implementation of on-board diagnostic testing as a mandatory testing element for 1996 and newer vehicles equipped with second generation on-board diagnostics systems. Other June 2002 State I/M regulatory amendments reflect changes in the way the program was being operated since the regulations had previously been amended in 1999. As was stated earlier, Virginia incorporated regulatory updates to reflect changes in Federal and State law relevant to the I/M program. Finally, some changes were made to improve the Commonwealth's ability to oversee the program and to aid in enforcement of the program.

Virginia submitted its revised regulation as a formal SIP revision to EPA on December 18, 2002, with a technical correction amendment submitted on April 2, 2003. Below is a summary of the most significant changes to the Commonwealth's vehicle emission inspection program regulations submitted as part of the December 18, 2002 SIP revision:

1. Incorporates on-board diagnostic testing for OBD–II compliant vehicles and subjects OBD–II equipped 1997 and newer diesel-powered vehicles to the program for the first time.

2. Program coverage revised to exempt vehicles 25 years old and older at the time of testing, in lieu of the previous exemption of 1968 and older model vehicles.

3. Revision of acceleration-simulation mode (ASM) emission standards and removal of ASM test procedure pre-screening requirements.

4. Tightening of two-speed idle emission test standards, to reflect advanced technology and related lower emission levels of 1990 and newer vehicles.

5. Relaxation of roadside remote sensing standards, and greater flexibility for VA DEQ in use of various pollutants as roadside screening criteria.

6. Repeal of requirement for evaporative system purge testing.

7. Revision of requirements for Federal and private fleet testing and reporting, and addition of ''sensitive mission vehicle'' fleet emission inspection station permit category.

8. Revision of visible emissions standard to include a standard for diesel-powered vehicles now subject to OBD testing.

9. Elimination of deadlines for waiver limit increases that have already passed; and requirement for vehicles that received a waiver in another State to be tested if subject to Virginia's I/M program.

10. Repeal of requirements limiting warranty eligibility for certain emissions short tests.

11. Modification of penalty schedule for major violations related to emissions inspections.

12. Revision of a number of definitions to reflect related regulatory changes, and repeal of others that are no longer needed to support the Commonwealth's regulations.

A more detailed summary of each of these June 2002 regulatory changes is detailed below, with additional information provided in the technical support document prepared by EPA in support of this rulemaking action.

1. Addition of On-Board Diagnostics Inspections

Subject 1996 and newer subject vehicles equipped with second generation on-board diagnostics systems (OBD–II) will receive electronic checks of their on-board diagnostics systems in lieu of other emissions tests. An OBD check consists of a visual check of the dashboard indicators and an electronic examination of the OBD computer for potential stored fault information. OBD-equipped 1997 and newer light duty diesel vehicles are also required to be OBD tested.

Virginia's I/M regulation established a start date of October 2002 to commence mandatory OBD checks of gasoline-powered vehicles under its I/M program, with the option to delay testing if the VA DEQ determined its OBD test equipment was unavailable or not ready. After the occurrence of such an equipment-related delay, Virginia began mandatory OBD testing on gasoline-powered vehicles in November 2005. For the first time, Virginia's June 2002 regulation requires the addition of mandatory OBD checks for light duty diesel-powered vehicles, to begin no later than October 2006. However, in practice VA DEQ delayed diesel-powered OBD checks and instead began diesel OBD checks as part of the I/M program in May 2007 (for vehicles with registrations expiring July 2007).

For most vehicles subject to OBD checks under Virginia's program, an OBD check will be performed in lieu of tailpipe testing (i.e., ASM or 2-speed idle tests). However, VA DEQ may also perform exhaust tests on a limited basis, in addition to an OBD check, for quality control or program evaluation purposes. Some vehicles that are known to have OBD system problems may be exempted by VA DEQ from an OBD check and instead be given tailpipe tests. Vehicles whose OBD system is determined to be ''not ready'' to be checked, as defined by Virginia regulation, will be rejected from testing.

2. Model Year Coverage Revised to Exempt 25-Year-Old and Older Vehicles From Testing

Virginia revised its I/M program model year coverage, moving to a rolling exemption for vehicles 25 years and older at the time of inspection, in place of its previous age-based exemption for 1968 and older vehicles. Virginia statute required this change, and DEQ has implemented this practice since July 2000. The change results in a decrease in the number of cars being tested under the I/M program, as each year another model year is exempted. In 2004, the last year Virginia provided data, VA DEQ estimated this model year coverage change would result in the testing of approximately 19,400 fewer vehicles. Virginia estimates that this will result in an increase of volatile organic compound (VOC) emissions of approximately 0.55 tons per day in 2002, or about 3.5% of the total VOC emissions reductions associated with the I/M program. No nitrogen oxide (NO_X) penalty has been associated with this change, as the vehicles affected would have been tested with idle testing (in the 2002 and 2005 evaluation timeframes for which I/M programs were required to be evaluated under the Federal I/M rule). Virginia did not calculate carbon monoxide (CO) impacts from this change, as the Northern Virginia region is classified as CO attainment, and a CO emissions inventory for this timeframe was unavailable. Virginia has modeled the 25-year rolling exemption in the attainment demonstration and reasonable further progress plans for the Metropolitan Washington DC 1-hr ozone nonattainment area.

3. Revision of ASM Test Standards/ Removal of ASM Test Procedure Pre-Screening Requirements

Virginia's June 2002 I/M regulation revised the testing standards, or cutpoints, for determining whether vehicles pass or fail Virginia's 2-mode ASM 5015/2525 tailpipe emissions test. Virginia had previously required that start-up standards were to be used for one year after program implementation, per EPA's ASM technical guidance document entitled ''Acceleration Simulation Mode Test Procedures, Emissions Standards, Quality Control Requirements, and Equipment Specifications'' (draft dated July 2000, final dated July 2004). Virginia's 2002 revised rule applies final ASM standards, unless VA DEQ determines that phase-in standards or interim standards (i.e., less stringent than final, but more stringent than phase-in standards) should be used. Such a determination would be based upon results of emissions inspections from ASM tests performed under the program and after consultation with vehicle manufacturers, EPA, and appropriate research organizations. Virginia also removed ASM test standards for those model year vehicles no longer subject to testing, due to its age-based exemption for vehicles older than 25 years.

4. Revision of 2-Speed Idle Test Standards

Under the June 2002 I/M rule revision, Virginia enacted more stringent emissions test standards, or cutpoints, for 2-speed idle tailpipe emissions testing conducted on some 1990 and newer vehicles. VA DEQ determined that more stringent 2-speed idle testing was justified, based upon an analysis of failure rates for these vehicles subject to 2-speed idle testing and also by reviewing standards and fail rates from other programs that use 2-speed idle testing. Previously, 1990 and newer vehicles having advanced technology needed only to meet standards applicable to 1981 and older vehicles. Some of these newer, advanced technology vehicles with known faults were able to pass the test under the previous, less stringent standard for 1981 and older vehicles. The revised 2-speed idle cutpoints are 110 parts per million (ppm) of hydrocarbon (HC) and 0.75% carbon monoxide (CO), where they had been 220 ppm HC and 1.2% CO. Virginia has been testing under these more stringent cutpoints since October 2002. As part of the SIP, VA DEQ estimated the number of additional vehicles that would fail with the more stringent standards in place. For 2004, which was the latest year for which Virginia provided an estimate, about 800 additional vehicles were expected to fail than would have if the less stringent standards had remained in place.

5. Relaxation of Roadside Remote Sensing Standards and Flexibility for VA DEQ To Use Various Pollutants for Roadside Screening Criteria

Roadside remote sensing program requirements were revised by Virginia in its June 2002 revised I/M program rule. Remote sensing is used to ensure motorist compliance with the program. Remote sensing reads a vehicle as it passes by a roadside sensor, after which the vehicle's emissions are checked against standards set by the state. In the case of Virginia's remote sensing program, if the vehicle is checked twice in a 90-day period and has emissions beyond the standards, the owner may be required to undergo an out-of-cycle emissions test. Virginia relaxed its remote sensing emissions standards as part of the June 2002 I/M rule revision to avoid the potential for false failures of the remote sensing test (i.e., to avoid failing vehicles using remote sensing that would otherwise pass regular tailpipe emissions or OBD checks). Putting aside differences between Virginia's regular tailpipe tests versus a remote sensing test, there is a level of uncertainty when comparing vehicles in a station tailpipe testing environment versus roadside remote sensing. Virginia revised its remote sensing test standards to ensure an adequate margin of error to avoid subjecting motorists to unnecessary out-of-cycle emissions tests. Virginia also revised its remote sensing test criteria to allow VA DEQ to use HC or CO, or a combination of both, as criteria for remote sensing pass or fail.

At the time of the December 2002 SIP revision, Virginia had not yet performed mandatory remote sensing testing as part of its I/M program. Virginia subsequently conducted a pilot remote sensing program to evaluate potential problems with remote sensing prior to use of remote sensing as a mandatory element of the I/M program, and as a result subsequently revised its remote sensing program. Those changes, as well as others related to remote sensing as a tool to ensure ongoing motorist compliance were submitted as part of the June 18, 2007 SIP revision, and are discussed below, in the portion of this rulemaking related to that SIP submittal. EPA is taking action on both the December 18, 2002 SIP revision, and the later, June 18, 2007 SIP revisions, which updated the December 18, 2002 provisions. Where the same regulatory provisions are included in both SIP submittals, EPA is proposing to take action on the most recent version of the regulatory provisions.

6. Revision of Requirements for Evaporative System Pressure and Purge Testing

As part of its June 2002 regulatory revisions, Virginia removed the requirement to conduct evaporative system purge testing from the I/M program. Purge testing was a means to measure the instantaneous purge flow from the vehicle's evaporative canister to the engine's intake manifold, in order to ensure proper operation of the evaporative system. The purge test was to have been performed in conjunction with ASM testing beginning in 1999. In a November 5, 1996 policy memo, EPA determined purge testing to be intrusive and potentially damaging, and therefore

did not enforce the implementation of this requirement. A suitable alternative test has never materialized, and the latest version of EPA's emission factor model, MOBILE6, has eliminated any HC emissions benefit associated with purge testing. Virginia never implemented purge testing as part of its I/M program, and EPA has never acted to enforce that SIP provision of Virginia's prior approved SIP. Given this reality, Virginia removed purge testing as an element of the I/M program in its June 2002 revised rule.

Implementation of evaporative pressure testing has been left to the discretion of VA DEQ. The evaporative pressure test is a test to measure levels of evaporated fuel between the fuel tank and the engine to ensure the system is not compromised and releasing these emissions to the ambient air. Virginia's prior approved SIP required evaporative emissions testing to have begun in 1998, but such testing was delayed due to technical limitations of the pressure test. EPA acknowledged difficulties with evaporative canister-based pressure testing in a November 5, 1996 policy memo (as well as discussing a potential fill pipe-based alternative in conjunction with gas cap testing). Virginia revised its I/M rule in June 2002 to indefinitely delay implementation of pressure testing as an element of Virginia's I/M program, to a date to be determined the director of the VA DEQ (with at least one year notification to station owners in the event the test is to be implemented).

It should be noted that modern OBD systems have sensors to detect leaks in the evaporative system, and to monitor the purge system, so 1996 and newer vehicles will be have their evaporative systems monitored via an OBD check as part of the program. The MOBILE model now reflects emissions benefits from this check of newer vehicles.

7. Revision of Requirements for Federal and Private Fleet Testing and Reporting

Virginia made several changes with respect to the testing of federal fleet vehicles in its December 2002 SIP revision. Under the prior approved SIP, federal fleets had been required to submit compliance reports to VA DEQ, while private fleets were not subject to compliance reporting. Virginia revised its I/M program rule in June 2002 to rescind the requirement that administrators of federal fleets submit reports to VA DEQ to demonstrate fleet compliance, thus treating federal and private fleets equally. At the same time, Virginia repealed a related requirement for federal fleets to remit a $2 annual fee for each vehicle not registered with the Virginia Department of Motor Vehicles.

Virginia also added ''sensitive mission vehicle emissions fleet inspection station'' to the list of qualified applicants who can apply to VA DEQ for inspection station permits. This change allows agencies such as the Central Intelligence Agency and Federal Bureau of Investigation to establish inspection stations, in order to avoid potential exposure of their sensitive mission vehicles (as defined under Virginia's I/M rule) when undergoing emissions testing.

8. Revision of Visible Emissions Standard To Include a Standard for Diesel-Powered Vehicles Subject to OBD Testing

Virginia added a standard for visible air pollutant emissions for diesel-powered vehicles that are now subject to OBD testing as part of Virginia's I/M program in its June 2002 rule revision. The standard limits emission of visible air pollutants from the tailpipe of a subject diesel vehicle to a density of no more than 20% opacity for longer than 10 consecutive seconds (after the engine reaches operating temperature), per Reference Method 9.

9. Elimination of Deadlines for Waiver Limit Increases That Have Already Passed and Established Criteria for Issuance by VA DEQ of Temporary Waiver If Necessary Repair Parts Are Not Available

Repair waivers are a form of I/M program compliance that allow the motorist to comply with an I/M program without meeting the applicable test standard. A waiver may be issued if the vehicle fails an inspection, undergoes qualifying repairs up to a program-designated repair cost waiver limit, and then fails its retest. EPA rules allowed programs to phase-in waiver limits to a statutory limit of $450, adjusted by the Consumer Price Index (CPI). Virginia removed phase-in deadlines for full waiver cost compliance under the June 2002 I/M rule revision, instead stating that beginning January 2003 waiver eligibility shall be $450 adjusted to reflect the increase in the CPI.

Virginia amended its June 2002 I/M rule to include criteria for issuance of a temporary waiver due to unavailability of components necessary to complete repairs to pass the test or to qualify for a waiver. To obtain a temporary waiver, the motorist must provide a signed statement from an owner of a parts supplier stating that needed parts are unavailable, including a description and part number(s) of said parts.

10. Repeal of Requirements Limiting Warranty Eligibility for Certain Emissions Short Tests

Virginia repealed its short test standards for warranty eligibility (9 VAC 5–91–470) in its June 2002 rule revision. In the past, this language had served to ensure that short test emissions results did not exceed 220 ppm of HC and 1.2% CO. However, with the June 2002 revision of Virginia's 2-speed idle test standards and the change in I/M program model year coverage to vehicles 25 years and newer, there are no longer any vehicles subject to I/M (and which are eligible for federal emissions warranty coverage) for which test cutpoints exceed the threshold of 220 ppm HC and 1.2% CO. Therefore, the warranty eligibility provisions of 9 VAC 5–91–470 are no longer relevant, and have thus been repealed by Virginia.

11. Modification of Penalty Schedule for Major Violations Related to Emissions Inspections

In their June 2002 I/M rule revision, Virginia revised their list of regulatory provisions (9 VAC 5–91–620) of which a violation constitutes a major violation. Major violations are defined by Virginia as the most serious offenses resulting from unacceptable performance in conducting emissions inspections that would directly affect the credibility, integrity, and emissions reductions associated with the I/M program. Virginia indicated in the SIP revision that this revised list of provisions (of which a violation constitutes a major violation) is a reflection of the additional flexibility incorporated in the revised regulation for emission inspection procedures.

12. Revision of a Number of Definitions To Reflect Related Regulatory Changes, and Repeal Others That Are No Longer Needed To Support the Commonwealth's Regulations

Virginia revised a number of its definitions of terms in 9 VAC 5–91–20, and repealed others altogether, in support of other changes made to the Commonwealth's I/M rule in June 2002. Some terms were also revised for improved clarity, while others were revised to correct cross-references to other revised regulatory sections.

Terms that were revised include: access code; actual gross weight; affected motor vehicle; air system; alternative fuel; certified enhanced analyzer system; chargeable inspection; curb idle; dedicated alternative fuel vehicle; emissions control systems; enhanced emissions inspection

program; evaporative system pressure test; flexible fuel vehicle; formal hearing; fuel filler cap pressure test; gross vehicle weight rating (GVWR); informal fact finding; inspection fee; motor vehicle; motor vehicle inspection report; on-board diagnostic system (OBD system); on-board diagnostic system test (OBD system test); on-board diagnostic vehicle (OBD vehicle); operated primarily; reinspection or retest; remote sensing; thermostatic air cleaner; two-speed idle test (TSI); and vehicle specific power (VSP).

Terms that were repealed include: aborted test; alternative evaporative system purge and pressure test; emissions repair facility; emissions repair technician; evaporative system purge test; federal employee; federal facility; gross weight; inspector access code; inspector number; original equipment manufacturer (OEM); state implementation plan; thermometer, certified; and Tier 1.

Terms that were newly added by Virginia include: aborted test; emissions control equipment; identification number; and implementation plan (replacing state implementation plan, which has been removed).

In addition to the items detailed above, Virginia made several other changes to the I/M rule as part of the December 18, 2002 SIP revision that are organizational in nature, or are otherwise minor in importance, and are not discussed in detail in this action. Please refer to the technical support document prepared in support of this action, or to this version of the Commonwealth's I/M regulation, which was published in the *Virginia Register of Regulations* on June 17, 2002 and can be found in the docket for this action.

B. Virginia's June 18, 2007 SIP Revision

Virginia again revised its I/M program regulations codified in Title 9, Chapter 91 of the Virginia Code in a final rule published in the *Virginia Register of Regulations* on May 30, 2005 (Volume 21, Issue 19). Virginia submitted this latest version of its I/M regulation (9 VAC 5–91) as part of a June 18, 2007 SIP revision submitted to EPA. The submitted portions of this more recent version of the Commonwealth's I/M regulation supersedes those portions of 9 VAC 5–91 published earlier that were submitted to EPA in the prior SIP submittal (i.e., the December 18, 2002 SIP revision). Where Virginia has submitted the same regulatory provisions in separate SIP revisions, EPA is proposing to act upon the later version of the regulation.

The Commonwealth's May 2005 regulation serves to make a number of changes to Virginia's roadside testing program (i.e., remote sensing) provisions of the regulation. The remote sensing program is a roadside test to ensure that vehicles primarily operated in the I/M program area do not grossly exceed emissions limits set by the I/M program. The program serves both to identify high emitting vehicles subject to regular I/M checks, and to monitor vehicles that are not subject to traditional biennial emissions inspections in Virginia. Roadside testing can serve to identify subject vehicles that have become high emitters since their last regular biennial emission inspection, or that may have been high emitters at the time of their most recent inspection but passed that test in error. Roadside remote sensing observations may require motorists with vehicles identified as high emitters by roadside testing to undergo an additional ''off cycle'' I/M inspection, or in the alternative to pay a civil penalty.

In general, the Commonwealth amended the regulation to reflect new remote sensing emissions standards, and the criteria for conducting random, roadside ''off-cycle'' testing of motor vehicle emissions, as well as protocols for testing and procedures to notify owners of test results.

The Commonwealth's regulatory changes relate primarily to:

1. Changes in remote sensing model year applicability, relating to vehicles subject to remote sensing;
2. Protocols for determination of gross polluters and clean car screening;
3. Changes to remote sensing test procedures;
4. Changes to remote sensing test standards;
5. Financial assistance provisions;
6. Changes in enforcement and compliance procedures; and
7. Changes to regulatory definitions.

A summary of these changes made by Virginia under the May 2005 final rule are detailed below:

1. Changes in Remote Sensing Model Year Applicability

Virginia amended its regulation in order to comply with changes to the Code of Virginia. Model year coverage, with respect to remote sensing under 9 VAC 5–91–180, was expanded to include vehicles of model year 1968 and newer. Previously, applicability for remote sensing was limited to those ''affected vehicles'' subject to I/M testing (i.e., the 25 most recent model years). The Commonwealth also revised their definition of ''operate primarily'' (for purposes of remote sensing) to include a vehicle observed by roadside remote sensing equipment at least three times in a two-month period (with no less than 30 days between the first and last readings). Vehicles exceeding the standards twice in any 120-day period (as opposed to the Commonwealth's previous requirement for 90-day observation period) will be determined to have violated the standards, and will require a confirmation test (ASM or OBD test) at an emission inspection station.

2. Protocols for Determination of High Emitting Vehicles and Clean Screening

Virginia has amended is protocols for determining whether a vehicle is a gross polluter. Virginia's ''high emitter index'' is a means of categorizing probable emission failure rates of engine families. The index is determined by calculating the historical emissions inspection failure rate (by vehicle model year, make, model, and engine size) to the historical emissions inspection failure rate of all the engine families in that same group. Failure rates are based on the most recent full year of emissions inspection test data. Vehicles with a high emitter index of greater than 75 are deemed high emitters.

Beginning January 1, 2005, motor vehicles that exceed the Virginia's remote sensing emissions standards on two separate days in any 120-day period shall be considered to have violated the emissions standards. In addition, the department may use the high emitter index as a screening requirement. Beginning July 1, 2005, based on analysis of remote sensing failure rates and confirmation test results, the VA DEQ may determine than an affected vehicle is a high emitter if the vehicle exceeds remote sensing standards a single time and has a ''high emitter index'' of greater than 75.

Beginning July 1, 2005, clean screening will be used by Virginia to identify affected vehicles eligible for an exemption from their next scheduled emissions test. Up to five percent of the total vehicles measured by on-road testing (i.e., remote sensing) during any 30-day period may be identified as ''clean screen vehicles''. At the discretion of VA DEQ, vehicles identified as such may receive a ''pass'' for their next scheduled emissions test, without undergoing a regular, biennial emissions inspection.

3. Changes to Remote Sensing Test Procedures

Virginia has amended its exhaust emissions standards for its remote sensing program. Beginning July 1, 2005, motor vehicles determined to exceed roadside remote sensing standards after two or more

measurements in any 120-day period, shall be considered to have violated emissions standards and shall be subject to an off-cycle, confirmation test. A vehicle exceeding the remote sensing standards a single time (which is also determined by the VA DEQ to have a ''high emitter index'' greater than 75) will be subject to an off-cycle, confirmation test.

Vehicles subject to confirmation testing may be subject to the applicable emissions test for their vehicle, and vehicles 1996 and newer may be subject to exhaust testing, in addition to an OBD system test. A failed confirmation inspection (ordered by VA DEQ due to a roadside, remote sensing test failure) will be a chargeable inspection, while a passing confirmation test will not result in a test fee.

4. Changes to Remote Sensing Test Standards

Virginia has revised its remote sensing exhaust emission standards to establish separate standards for light-duty gasoline vehicles (i.e., passenger cars), light-duty gasoline trucks, and heavy-duty gasoline vehicles. Additionally, Virginia has established standards that apply in the case where two or more on-road, remote sensing measurements are gathered for an applicable vehicle over a 120-day period. Separate standards apply in the case of a single on-road measurement, where a vehicle is also determined by VA DEQ to have a ''high emitter index'' of 75 or more.

Virginia has for the first time established nitric oxide (NO) remote sensing standards, in addition to existing standards for HC and CO.

All remote sensing measurements are to be measured based upon vehicle specific power (VSP), which is a means of utilizing vehicle speed, drag coefficient, tire rolling resistance and roadway grade to characterize the load under which a vehicle is operating at the time a remote measuring measurement is taken. Only valid remote sensor measurements with a VSP between 3 and 22 shall be used to determine if a vehicle violates the remote sensing standards.

Finally, Virginia amended its 2-speed idle exhaust emissions test standards to add standards for 1968–1974 model year vehicles. These vehicles were no longer subject to regular, biennial emissions testing under Virginia's June 2002 regulatory amendments, but are now affected motor vehicles subject to roadside remote sensing tests, and, if necessary, follow-up, 2-speed idle confirmation testing.

5. Financial Assistance Provisions

Virginia's amended regulation establishes a financial assistance program to subsidize repair costs of some vehicles determined to be in violation of roadside remote sensing standards. Qualified individuals may receive up to 50% of the cost of emission-related repairs or up to 50% of the waiver amount (after a co-payment of $100). To qualify, an individual must be the registered owner of the vehicle (registered in the program area), have a household income less than 133% of federal poverty guidelines, and the vehicle must have a valid safety inspection. Only individual vehicle owners are eligible for assistance—commercial, non-profit, and government vehicles are ineligible.

Remote sensing roadside testing has been expanded to include vehicles previously not subject to remote sensing. These affected vehicles include those newer than model year 1968 (versus the previous coverage of vehicles 25 model years old, or newer).

6. Changes to Enforcement and Compliance Procedures

Upon determination by VA DEQ that a roadside, remote sensing violation occurred, motorists will be informed in writing by that department of such failure. Motor vehicle owners that receive a notice of violation of roadside, remote sensing standards will be required to furnish proof that their vehicle passed a confirmation test or received a waiver within 30 days of a notice of violation of remote sensing standards. At that time, civil charges will be assessed (unless the vehicle is due for its regularly scheduled biennial emissions test within 3 months of the date of the measured violation of the remote sensing standard).

Civil charges assessed for failure to pass (or receive a waiver) from a confirmation test are to be based upon the degree by which the vehicle exceeds the remote sensing standards. Violations up to 150% of the applicable standard will result in a charge of no more than 50% of the cost of a program waiver (i.e., $450, adjusted annually by the 1990 Consumer Price Index). Violations over 150% of the applicable remote sensing standard will result in a civil charge no more than 100% of a program waiver.

7. Changes to Regulatory Definitions

Virginia revised several definitions in 9 VAC 5–91–120 in its May 30, 2005 regulatory amendment. The definitions of the following terms were revised: affected motor vehicle; light duty truck (LDT); light duty truck (LDT1); light duty truck (LDT2); light duty vehicle; and operated primarily.

Definitions for the following terms were added to 9 VAC 5–91–120: confirmation test; heavy duty gasoline vehicle (HDGV); high emitter index (HEI); light duty gasoline vehicle (LDGV); light duty gasoline truck (LDGT1); light duty gasoline truck (LDGT2); and vehicle specific power (VSP).

IV. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) ''privilege'' for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information (1) that are generated or developed before the commencement of a voluntary environmental assessment; (2) that are prepared independently of the assessment process; (3) that demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) that are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information ''required by law,'' including documents and information ''required by Federal law to maintain program delegation, authorization or approval,'' since Virginia must ''enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts * * *.'' The opinion concludes that

''[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval.''

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that ''[t]o the extent consistent with requirements imposed by Federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.''

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

V. Proposed Action

EPA is proposing to approve Virginia's revisions to the enhanced I/M program SIP for the Northern Virginia I/M program area. These SIP revisions were formally submitted to EPA by the Commonwealth on December 18, 2002, on April 2, 2003, and on June 18, 2007. EPA's review of this material indicates that the Commonwealth's revisions to the prior, SIP-approved I/M program continue to adhere to Federal requirements applicable to enhanced inspection and maintenance programs.

EPA reviewed the Commonwealth's revisions to the enhanced I/M program in accordance with requirements for inspection and maintenance programs in sections 182 and 184 of the Clean Air Act, and with Federal rule requirements for I/M programs, codified at 40 CFR part 51, subpart S.

Many of these changes made by the Commonwealth's most recent SIP revisions have been in effect in Virginia's program since October 1, 2002, with some state statutory-driven changes having taken effect earlier (e.g., model year coverage changes) and some changes phased in according to later state regulatory deadlines (e.g., separate provisions for mandatory OBD testing for gasoline-powered vehicles and diesel-powered vehicles). The Commonwealth's revised roadside testing program (i.e., remote sensing) regulatory changes have a state effective date of June 2005. However, some of the provisions of these rules had delayed or phased-in implementation and began more recently, such as light duty diesel OBD testing.

These revisions to the Commonwealth's I/M program have already taken effect at the state level, and implementation of these provisions has been noncontroversial at the state level. Virginia has relied upon the revised I/M program (including the 2002 regulatory changes to the program) as the basis for its modeling of the Greater Washington DC Metropolitan area 1-hour ozone attainment demonstration and rate-of-progress plans, and this most recent iteration of the program (*i.e.*, the Commonwealth's May 2005 version of the I/M regulations) is modeled as a control measure for Virginia's attainment demonstration SIP for the Washington DC 8-hour ozone nonattainment plan. The revised I/M program continues to achieve VOC and NO_X emissions reductions toward meeting the ozone national ambient air quality standard. For additional information concerning EPA's review of Virginia's SIP revisions, please refer to the Technical Support Document prepared by EPA in support of this rulemaking.

EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

VI. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)). This action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This proposed rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely proposes to approve a state rule implementing a Federal requirement, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This proposed rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it approves a state rule implementing a Federal standard.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this proposed rule, EPA has taken the

necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This proposed rule to approve revisions to Virginia's enhanced I/M program SIP does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: February 6, 2008.

William T. Wisniewski,

Acting Regional Administrator, Region III.

[FR Doc. E8–2552 Filed 2–11–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2006–0665; FRL–8528–1]

Approval and Promulgation of Air Quality Implementation Plans; Texas; Texas Low-Emission Diesel Fuel Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the State Implementation Plan (SIP) for the state of Texas. This revision makes changes to the Texas Low-Emission Diesel (TXLED) Fuel program. The revision establishes a replicable procedure for the State to approve Alternative Emission Reduction Plans (AERPs), extends the date of state approvals, and brings marine diesel fuels under the TXLED program. The revision also refines and clarifies testing requirements. The changes being proposed for approval positively influence the reductions of oxides of nitrogen (NO_X) to be achieved. As a result and in accordance with section 110(l) of the Clean Air Act, 42 U.S.C. 7410(l), this revision will not interfere with attainment, reasonable further progress, or any other applicable requirement of the Clean Air Act.

DATES: Comments must be received on or before March 13, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R06–OAR–2006–0665, by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the on-line instructions for submitting comments.

• *U.S. EPA Region 6 ''Contact Us'' Web site: http://epa.gov/region6/r6coment.htm* Please click on ''6PD'' (Multimedia) and select ''Air'' before submitting comments.

• *E-mail:* Mr. Guy Donaldson at *Donaldson.guy@epa.gov.* Also cc the person listed in the **FOR FURTHER INFORMATION CONTACT** section below.

• *Fax:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), at fax number 214–665–7263.

• *Mail:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.

• *Hand or Courier Delivery:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Such deliveries are accepted only between the hours of 8 am and 4 pm weekdays except for legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R06–OAR–2006–0665. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. The file will be made available by appointment for public inspection in the Region 6 FOIA Review Room between the hours of 8:30 am and 4:30 pm weekdays except for legal holidays. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below or Mr. Bill Deese at (214) 665–7253 to make an appointment. If possible, please make the appointment at least two working days in advance of your visit. There will be a 15 cents per page fee for making photocopies of documents. On the day of the visit, please check in at the EPA Region 6 reception area at 1445 Ross Avenue, Suite 700, Dallas, Texas.

The State submittal is also available for public inspection at the State Air Agency listed below during official business hours by appointment:

Texas Commission on Environmental Quality, Office of Air Quality, 12124 Park 35 Circle, Austin, Texas 78753.

FOR FURTHER INFORMATION CONTACT: Ms. Sandra Rennie, Air Planning Section (6PD–L), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, telephone (214) 665–7367; fax number 214–665–7263; e-mail address *rennie.sandra@epa.gov.*

SUPPLEMENTARY INFORMATION:

Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This document concerns control of air pollution of NO_X and VOCs from mobile sources in 110 counties of East Texas where the rule applies. This low-emission diesel fuel program applies to both on-road and non-road vehicles in the affected area.

What Action Are We Taking Today?

We approved the original TXLED rule on November 14, 2001, (66 FR 57196) in conjunction with the Houston-Galveston One-Hour Attainment Demonstration SIP. We also approved revisions to this rule on April 6, 2005 (70 FR 17321), and on October 6, 2005 (70 FR 58325). Today we are proposing to approve revisions to the TXLED rule submitted May 15, 2006, June 11, 2007, and June 13, 2007. Among other things, the revisions establish a replicable procedure for the State to evaluate Alternative Emission Reduction Plans (AERPs) so that changes to those plans do not have to be submitted to EPA as a SIP revision. Both EPA and the Texas Commission on Environmental Quality view this approach as a way to conserve resources. The revisions also extend the expiration date for state-approved AERPs and require two forms of marine diesel fuel to be subject to TXLED requirements. Other less substantive revisions are listed in the next section.

What Did the State Submit?

On May 15, 2006, the State submitted revisions to TXLED rules found in 30 TAC 114.6, 114.312, 114.313, 114.315, 114.316, 114.317, and 114.318. These revisions were adopted by the State on April 26, 2006. These include revisions to definitions; low emission diesel standards; designated alternate limits; approved test methods; monitoring, recordkeeping, and reporting requirements; exemption to low emission diesel requirements; and alternative emission reduction plans.

On June 11, 2007, the State submitted revisions adopted on May 9, 2007, to § 114.318, Alternative Emission Reduction Plan. On June 13, 2007, the State submitted revisions adopted on May 23, 2007, to § 114.6, Definitions, and to § 114.319, Affected Counties and Compliance Dates.

Why Are These Revisions Approvable?

EPA finds that the TCEQ submittal meets the requirements of the CAA. We analyzed the rule revisions to ensure that they did not compromise the integrity of the approved SIP. Some changes were non-substantive editorial or format changes. Some substantive changes are considered minor. Major substantive changes are discussed below. A detailed analysis of all changes can be found in the Technical Support Document that accompanies this action.

Section 114.6. Definitions

The definition of additive is reworded for clarification. The definition of diesel fuel is expanded to include Diesel Marine fuel type X, also known as DMX, and Marine Gas Oil, also known as MGO. While these fuels do not share all fuel parameters with an EPA defined diesel fuel, EPA diesel and these marine fuels share many fuel parameters and are all light distillates. Because section 114.312(a) requires all ''diesel fuel'' to conform to TXLED standards or to an approved AERP, these marine fuels will now be subject to those requirements. Requiring these marine fuels to meet the TXLED requirements will cause these fuels to achieve the desired benefit, thereby ensuring further NO_X reductions.

Section 114.312. Low Emission Diesel Standards

Volatile organic compounds (VOCs) were removed from the list of emissions that were required to be comparable to those of TXLED for alternative fuel formulation testing. This change was made to be consistent with changes made elsewhere in the rule. Because this rule is a NO_X control measure, and not intended to produce VOC reductions, and because VOC emissions from diesel engines are very small in any case, we propose to find approvable the removal of the VOC comparison requirement. Past SIP submittals for attainment, such as the Dallas-Fort Worth 1-hour attainment demonstration (April 2000) and the Houston 1-hour attainment demonstration (December 2000), do not contain values for and do not rely on VOC benefit from the TXLED program.

Section 114.315. Approved Test Methods

The State added specificity and clarity to the approved rules by making the following changes. The correlation equation to be used with ASTM Test Method D5186 is now specified. This equation is the same equation that appears in the EPA-approved CARB diesel rules. The adopted rule now requires the Executive Director to consult with and obtain agreement from EPA before the State approves an alternative to a test method. Additional fuel properties must be taken into consideration in characterizing the candidate fuel used in alternative fuel formulation testing. These include API gravity index, viscosity at 40 degrees C, flash point, and distillation in degrees F. Additional requirements that the test engine must meet are specified. The test engine must have a minimum specified amount of operation before initiating testing and must operate within 110% of its certified emission levels. An alternative test sequence, which EPA had not previously acted upon, was deleted from the rule. For a fuel to qualify as a TXLED fuel under the alternative fuel formulation portion of the rules, EPA must also be satisfied with the testing demonstration. These revisions are approvable because the changes make the rule more clear and provide for EPA involvement where necessary.

Section 114.316. Monitoring, Recordkeeping, and Reporting Requirements

Reporting on the additive used in an alternative fuel formulation is shifted from simply the amount used to a demonstration of how the emission reductions are achieved in the AERP. This strengthens the rule by making it more enforceable.

Section 114.318. Alternative Emission Reduction Plans

The AERP allows a diesel fuel producer to comply with the NO_X reduction requirements of TXLED by employing an alternate fuel strategy. In the May 15, 2006, revision a replicable procedure is outlined that removes the requirement for all AERP changes to be approved by EPA with a SIP revision. The procedure describes in detail how a producer can meet the requirements of this section by complying with one or more methods laid out in this section of the rule. Several methods utilize credit for the early introduction of low sulfur gasoline. We had detailed discussions with the State and refiners to reach consensus on these methods. The amount of sulfur reduction from the early introduction of low sulfur gasoline is used to calculate the appropriate gasoline-to-diesel offset ratios. We find the replicable procedure presented in the SIP to be an approvable approach to handling changes to AERPs.

The June 11, 2007 revision extends the expiration date for state-approved AERPs from December 31, 2006 to December 31, 2007. The purpose of extending this date was to provide time for producers and vendors to complete testing of alternative fuel formulations and additives, which in turn would provide more options in the marketplace to comply with the rule requirements. We found that this date extension had no impact on the path to the 2009 attainment year. Therefore this date extension is approvable.

Section 114.319. Affected Counties and Compliance Dates

This section is amended to set a phased compliance schedule for the implementation of the marine diesel requirements. Producers and importers must comply by October 1, 2007, bulk distributors must comply by November

15, 2007, and retail dispensers and other affected persons must comply by January 1, 2008. Whereas all 110 counties are covered in this section, the revision covering marine fuels applies only to the HGB nonattainment area counties of Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, and Waller.

Proposed Action

We are proposing approval of these revisions to the TXLED rule as submitted May 15, 2006, June 11, 2007, and June 13, 2007. The revisions being proposed for approval maintain the potential for the projected NO_X reductions to be achieved. As a result, and in accordance with section 110(l) of the Act, 42 U.S.C. section 7410(l), these revisions will not interfere with attainment, reasonable further progress or any other applicable requirement of the Clean Air Act.

Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this proposed action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*). Because this action proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This proposed action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon Monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401, *et seq.*

Dated: January 23, 2008.

Richard E. Greene,

Regional Administrator, Region 6.

[FR Doc. E8–2556 Filed 2–11–08; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[WC Docket No. 07–245; FCC 07–187]

Implementation of Section 224 of the Act; Amendment of the Commission's Rules and Policies Governing Pole Attachments; Correction

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects the reply comment date for a proposed rule published in the **Federal Register** of February 6, 2008. The corrected reply comment date is April 7, 2008.

FOR FURTHER INFORMATION CONTACT: Jonathan Reel, 202–418–0637.

Correction

In proposed rule FR Doc. E8–2177, beginning on page 6879 in the issue of February 6, 2008, make the following corrections:

1. On page 6879, in the Dates section, in the 2nd column, ''Reply Comments are due March 24, 2008'' is corrected to read ''Reply Comments are due April 7, 2008''.

2. On page 6879, in the Supplementary Information section, in the 2nd column, change ''Reply Comments on or before March 24, 2008'' is corrected to read ''Reply Comments on or before April 7, 2008''.

3. On page 6883, in the Initial Regulatory Flexibility Analysis section, in paragraph 19, in the 2nd column, ''Reply Comments are due on March 24, 2008'' is corrected to read ''Reply Comments are due on April 7, 2008''.

4. On page 6883, in the Initial Regulatory Flexibility Analysis section, in paragraph 21, in the 2nd column, ''Reply Comments are due March 24, 2008'' is corrected to read ''Reply Comments are due April 7, 2008''.

Federal Communications Commission.

Ruth A. Dancey,

Associate Secretary.

[FR Doc. E8–2564 Filed 2–11–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MB Docket No. 07–198; DA 08–113]

Review of the Commission's Program Access Rules and Examination of Programming Tying Arrangements

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of reply comment period.

SUMMARY: The Media Bureau extends the reply comment deadline on the Notice of Proposed Rulemaking (NPRM) on revisions to the Commission's program access and retransmission consent rules and whether it may be appropriate to preclude the practice of programmers to tie desired programming with undesired programming. To facilitate the development of a thorough record, the deadline for filing reply comments in response to the NPRM is extended to February 12, 2008.

DATES: Reply comments are due on or before February 12, 2008.

ADDRESSES: You may submit comments, identified by MB Docket No. 07–198, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Konczal, *David.Konczal@fcc.gov,* of the Media Bureau, Policy Division, (202) 418–2120.

SUPPLEMENTARY INFORMATION: This is a summary of the Order in MB Docket No. 07–198, DA 08–113, released on January 17, 2008. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street, SW., CY–A257, Washington, DC 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) The complete text may be purchased from the Commission's copy contractor, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Summary of the Order

1. On October 1, 2007, the Commission released an NPRM on revisions to the Commission's program access and retransmission consent rules and whether it may be appropriate to preclude the practice of programmers to tie desired programming with undesired programming. The NPRM set deadlines for filing comments and reply comments at 30 and 45 days, respectively, after publication of a summary of the NPRM in the **Federal Register**. A summary of the NPRM was published in the **Federal Register** on October 31, 2007, 72 FR 61590, October 31, 2007. Accordingly, the filing dates were initially established as November 30, 2007 for comments and December 17, 2007 for reply comments. On November 20, 2007, the Media Bureau released a Public Notice extending the time for filing comments to January 4, 2008, and the time for filing reply comments to January 22, 2008 (72 FR 73744, December 28, 2007).

2. The Walt Disney Company (Disney), Fox Entertainment Group, Inc. and Fox Television Holdings, Inc. (Fox), and Viacom Inc. (Viacom) filed motions seeking a 30-day extension of the reply comment deadline. The parties argue that the instant proceeding is complex, fact-intensive, and requires parties to review over a thousand pages of comments. The parties contend that the eighteen-day period between the comment and reply comment deadlines does not provide sufficient time for parties to respond effectively. The parties submit that additional time to prepare reply comments will cause no hardship or prejudice to other interested parties or to the Commission and will facilitate the development of a meaningful record.

3. As set forth in § 1.46 of the Commission's rules, the Commission's policy is that extensions of time for filing comments in rulemaking proceedings shall not be routinely granted. 47 CFR 1.46. In this case, however, an extension of the reply comment period is warranted to enable commenters to adequately review and respond to the extensive comments filed in response to the NPRM. We decline, however, to grant the full extension requested by the parties. With the additional extension granted herein, interested parties will now have a total of 39 days to prepare reply comments. As the parties note, this is longer than the 30-day reply period provided in other recent proceedings. We believe that this provides parties with ample time to respond to the comments filed in response to the NPRM.

4. Accordingly, to the extent described above, we hereby grant the Motions for Extension of Time filed in MB Docket No. 07–198 by Disney, Fox, and Viacom. The time for filing reply comments is extended to February 12, 2008.

5. This action is taken pursuant to authority found in sections 4(i), 4(j), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), and 303(r), and §§ 0.61, 0.283, and 1.46 of the Commission's rules, 47 CFR 0.61, 0.283, and 1.46.

6. Specific instructions for filing comments are located at paragraphs 26–27 of the item as published in the **Federal Register** and at paragraphs 139–142 of the item as released by the Commission and that appears on the Commission's Web site: *http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-07-169A1.doc*

Federal Communications Commission.

Steven A. Broeckaert,

Senior Deputy Chief, Policy Division, Media Bureau.

[FR Doc. E8–2566 Filed 2–11–08; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 73, No. 29
Tuesday, February 12, 2008

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, Department of Commerce.

ACTION: Notice and Opportunity for Public Comment.

Pursuant to Section 251 of the Trade Act of 1974 (19 U.S.C. 2341 *et seq.*), the Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. EDA has initiated separate investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each firm contributed importantly to the total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT

[January 1, 2008 through January 31, 2008]

Firm	Address	Date accepted for filing	Products
Master Solutions, Inc	PO Box 4444, 20 Wolfbridge Road, Carlisle, PA 17013.	1/2/2008	Material handling systems; automatic truck loading systems; and specialty trailer manufacturing.
Advanced Cast Products, Inc	18700 Mill Street, Meadville, PA 16335.	1/3/2008	Manufactures ductile iron parts for a variety of industries.
The William L. Bonnell Company, Inc.	25 Bonnel Street, Newman, GA 30263.	1/3/2008	
John J. Steuby Company	6002 N. Lindbergh, Hazelwood, MO 63042.	1/4/2008	
Century Specialty Windows, Inc.	#1 Flair Road, US Highway 72, Lumberton, NC 28358.	1/7/2008	The company manufactures and markets decorative specialty windows, clear and decorative glass inserts and window operating hardware to domestic markets.
TGZ Acquisition Company, LLC dba JACE.	2 Pin Oak Lane, Suite 200, Cherry Hill, NJ 08003.	1/8/2008	Manufactures, sells, and rents Continuous Passive Motion (CPM) and electrotherapy devices.
Boyce Highlands, Inc	14 Whitney Road, Concord, NH 03301.	1/8/2008	Custom-made solid wooden moldings, both finished & unfinished.
Steel Parts Manufacturing	801 Berryman Pike, Tipton, IN 46072.	1/8/2008	Parts of clutches and similar stamped steel transmission components for the automotive industry.
Sierra Midwest, Inc	3100 S. Santa Fe Street, Chanute, KS 66720.	1/10/2008	Single, double and multi-sided printed circuit boards.
AFC Stamping & Production, Inc.	4900 Webster St, Dayton, OH 45414.	1/14/2008	Metal stampings for the motor vehicle, appliance, medical device and other industries.
Century Industries, Inc	2300 E 145th St, Little Rock, AR 72206–5809.	1/14/2008	Folding attic stairways.
AFC Stamping & Production, Inc.	4900 Webster St, Dayton, OH 45414.	1/14/2008	Metal stampings for the motor vehicle, appliance, medical device and other industries.
Helton Inc	8700 Manchester Highway, Morrison, TN 37357.	1/16/2008	The company produces, markets and distributes thermoformed plastic products and cast urethanes, mainly to OEM manufactures for parts and final assemblies.
Kitco, Inc	520 N Enterprise Drive, Warrensburg, MO 64093.	1/17/2008	Fiberglass parts.
Schuetz Tool & Die, Inc	807 Utah St, Hiawatha, KS 66434.	1/18/2008	Tools, Dies, and Parts.
LuSys Laboratories	3716 Camel View Road, San Diego, CA 92130.	1/24/2008	One-Step Diagnostic Rapid Test—Manufacturing process: Manufacture test strip into plastic cassette, seal into a foil pouch, place 25 pouches into a commercial box, and ship to customer.
Parmelee Industries, Inc. dba U.S. Safety.	8101 Lenexa Drive, Lenexa, KS 66214.	1/31/2008	Eye and face protective gear.
Vinylex Corporation	2636 Byington-Solway Road, Knoxville, TN 37931.	1/31/2008	Manufactures thermoplastics: Piping, siding, profile tubing (raw materials: PVC & EVA plastics).

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Office of Performance Evaluation, Room 7009, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. Please follow the procedures set forth in Section 315.9 of EDA's final rule (71 FR 56704) for procedures for requesting a public hearing. The Catalog of Federal Domestic Assistance official program number and title of the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance.

Dated: January 11, 2008.

William P. Kittredge,

Program Officer for TAA.

[FR Doc. 08–570 Filed 2–11–08; 8:45 am]

BILLING CODE 3510–24–P

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Docket 5–2008]

Foreign–Trade Zone 244 - Riverside County, California, Application for Subzone, Skechers USA, Inc. (Footwear Distribution), Moreno Valley, California

An application has been submitted to the Foreign–Trade Zones (FTZ) Board (the Board) by the March Joint Powers Authority, grantee of FTZ 244, requesting special–purpose subzone status for the footwear warehouse/distribution facility of Skechers USA, Inc. (Skechers), in Moreno Valley, California. The application was submitted pursuant to the Foreign–Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on February 1, 2008.

The proposed subzone facility (113 acres, 1 building, 1.8 million sq. ft., with a possible expansion of an additional building of 500,000 sq. ft.) will be constructed at Redlands Blvd. and Theodore St., just south of Freeway 60, Moreno Valley, California. The facility will be used for quality control, repairing, repackaging, labeling, ticketing, warehousing and distribution of foreign–origin footwear for both the U.S. market and for re–export. None of the activities which Skechers is proposing to perform under zone procedures would constitute manufacturing or processing under the FTZ Board's regulations. The application indicates that FTZ procedures would be used to support Skecher's California–based distribution activity in competition with facilities abroad.

FTZ procedures would exempt Skechers from customs duty payments on foreign products that are re–exported, some 5 percent of the plant's shipments. On its domestic shipments, duty payments would be deferred until the products are entered for consumption. The company may also realize certain logistical benefits related to the use of direct delivery and weekly customs entry procedures. The application indicates that the savings from FTZ procedures would help improve the plant's international competitiveness. In accordance with the Board's regulations, a member of the FTZ staff has been designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is April 14, 2008. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to April 28, 2008).

A copy of the application will be available for public inspection at each of the following locations: March Joint Powers Authority, 23555 Meyer Drive, Riverside, California 92518; and, Office of the Executive Secretary, Foreign–Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Washington, D.C. 20230–0002.

For further information, contact Diane Finver at Diane__Finver@ita.doc.gov or (202) 482–1367.

Dated: February 1, 2008.

Andrew McGilvray,

Executive Secretary.

[FR Doc. E8–2569 Filed 2–11–08; 8:45 am]

Billing Code: 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

A–570–886

Polyethylene Retail Carrier Bags from the People's Republic of China: Notice of Partial Rescission of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: February 12, 2008.

FOR FURTHER INFORMATION CONTACT: Karine Gziryan, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–4081.

SUPPLEMENTARY INFORMATION:

Background

On August 2, 2007, the Department published a notice of opportunity to request an administrative review of the antidumping duty order on polyethylene retail carrier bags from the PRC for the period of August 1, 2006, through July 31, 2007 (''POR''). *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review*, 72 FR 42383 (August 2, 2007).

On August 30, 2007, Sea Lake Polyethylene Enterprises, Ltd., Shanghai Glopack, Inc., Everfaith International (Shanghai) Ltd., and Shanghai Hua Yue Packaging Products requested administrative reviews of their sales of polyethylene retail carrier bags to the United States during the POR. Also on August 30, 2007, Asia Dynamics, Inc., a U.S. importer, requested a review of Shanghai Yafu Plastics Industry Co., Ltd., a producer and exporter of polyethylene retail carrier bags during the POR. On August 31, 2007, Crown Polyethylene Products (Int'l) Ltd., requested an administrative review of its sales of polyethylene retail carrier bags to the United States during the POR. Pursuant to these requests, and requests for administrative review from three other companies, the Department initiated an administrative review covering nine producers/exporters of the antidumping duty order on polyethylene retail carrier bags from the PRC.

On September 25, 2007, the Department of Commerce (''the Department'') initiated administrative reviews of the antidumping duty order on polyethylene retail carrier bags from the People's Republic of China (''PRC'') for nine companies. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part*, 72 FR 54428 (September 25, 2007) (''*Initiation Notice*''). On September 28, 2007, Crown Polyethylene Products (Int'l) Ltd. withdrew its request for review. On October 22, 2007, Everfaith International (Shanghai) Ltd., and Shanghai Hua Yue Packaging Products withdrew their requests for review. On December 26, 2007, Sea Lake Polyethylene Enterprises, Ltd., and

Shanghai Glopack, Inc. withdrew their requests for review. Also, on January 17, 2008, Asia Dynamics, Inc. withdrew its request for review of Shanghai Yafu Plastic Industry Co., Ltd. Therefore, the Department is rescinding the administrative reviews of sales of polyethylene retail carrier bags to the United States from the PRC covering the POR for these six companies.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if a party that requested a review withdraws the request within 90 days of the date of publication of the notice of initiation. In this case, five of the six companies listed above withdrew their requests for administrative review of their POR exports of polyethylene retail carrier bags within 90 days from the date of initiation. No other interested party requested a review of these companies. Therefore, the Department is rescinding this review of the antidumping duty order on polyethylene retail carrier bags from the PRC with respect to Sea Lake Polyethylene Enterprises, Ltd., Shanghai Glopack, Inc., Everfaith International (Shanghai) Ltd., Shanghai Hua Yue Packaging Products, and Crown Polyethylene Products (Int'l) Ltd., in accordance with 19 CFR 351.213(d)(1).

Asia Dynamics Inc. withdrew its request for administrative review of its POR imports of polyethylene retail carrier bags produced and exported by Shanghai Yafu Plastic Industry Co., Ltd. after 90 days from the date of initiation. However, according to 19 CFR 351.213(d)(1) the Secretary may extend the time limit of 90 days if the Secretary decides that it is reasonable to do so. Although Asia Dynamics Inc., withdrew its request after the 90–day deadline, we find it reasonable to accept the withdrawal request because, on November 16, 2007, the Department issued a final scope ruling where it determined that plastic bags called ''Personal Belongings'' bags imported by Asia Dynamics Inc. from Shanghai Yafu Plastics Industry Co., Ltd. are not within the scope of the antidumping duty order covering polyethylene retail carrier bags from the PRC. *See* Memorandum from Abdelali Elouaradia, Office Director, to Stephen J. Claeys, Deputy Assistant Security, titled ''Final Scope Ruling for Asia Dynamics, Inc., and Medline Industries, Inc.'' dated November 16, 2007. As a result of this final scope ruling, the Department issued liquidation instructions directing U.S. Customs and Border Protection (''CBP'') to liquidate all entries of ''Personal Belongings'' bags imported by Asia Dynamics Inc. No other interested party requested a review of this company. For these reasons, the Department is rescinding this review of the antidumping duty order on polyethylene retail carrier bags from the PRC with respect to Shanghai Yafu Plastic Industry Co., Ltd. in accordance with 19 CFR 351.213(d)(1).

Assessment

The Department will instruct ''CBP'' to assess antidumping duties on all appropriate entries for Sea Lake Polyethylene Enterprises, Ltd., Shanghai Glopack, Inc., Everfaith International (Shanghai) Ltd., Shanghai Hua Yue Packaging Products, Shanghai Yafu Plastics Industry Co., Ltd., and Crown Polyethylene Products (Int'l) Ltd. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as a final reminder to importers for whom this review is being rescinded of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's assumption that reimbursement of antidumping duties occurred and subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders (''APOs'')

This notice also serves as a reminder to parties subject to APOs of their responsibility concerning the return or destruction of proprietary information disclosed under an APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is in accordance with section 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4) of the Department's regulations.

Dated: February 5, 2008.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E8–2568 Filed 2–11–04; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

A–201–805

Circular Welded Non–Alloy Steel Pipe and Tube from Mexico: Rescission of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce

SUMMARY: In response to requests from Hylsa S.A. de C.V. ''Hylsa'') and Mueller Commercial de México, S. de R.L. de C.V. (''Mueller''), respondents, and Southland Pipe Nipples Co., Inc. (''Southland''), an interested party, the Department of Commerce (''the Department'') initiated an administrative review of the antidumping duty order on circular welded non–alloy steel pipe and tube (''pipe and tube'') from Mexico. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 72 FR 73315 (December 27, 2007). This administrative review covers the period November 1, 2006, through October 31, 2007. We are now rescinding this review due to requests by all parties named above to rescind the review.

EFFECTIVE DATE: February 12, 2008.

FOR FURTHER INFORMATION CONTACT: John Drury or Angelica Mendoza, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Room 7866, Washington, DC 20230; telephone: (202) 482–0195 or (202) 482–3019, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published an antidumping duty order on pipe and tube from Mexico on November 2, 1992. *See Notice of Antidumping Duty Orders: Certain Circular Welded Non–Alloy Steel Pipe from Brazil, the Republic of Korea (''Korea''), Mexico, and Venezuela and Amendment to Final Determination of Sales at Less Than Fair Value: Certain Welded Non–Alloy Steel Pipe from Korea*, 57 FR 49453 (November 2,

1992). The Department published a notice of ''Opportunity to Request an Administrative Review'' of the antidumping duty order for the period November 1, 2006, through October 31, 2007, on November 1, 2007. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 72 FR 61859 (November 1, 2007). Hylsa requested that the Department conduct an administrative review of sales of merchandise covered by the order by Hylsa on November 30, 2007. Additionally, both Mueller and Southland requested that the Department conduct an administrative review of sales of merchandise covered by the order by Mueller on November 30, 2007. In response to the requests, the Department published the initiation of the antidumping duty administrative review on pipe and tube from Mexico on December 27, 2007. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 72 FR 73315 (December 27, 2007).

Hylsa withdrew its request for review with respect to Hylsa on January 11, 2008. Both Mueller and Southland withdrew their requests for review with respect to Mueller on January 15, 2008.

Rescission of the Administrative Review

Pursuant to 19 CFR § 351.213(d)(1), the Secretary will rescind an administrative review under this section, in whole or in part, if a party that requested a review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. The Secretary may extend this time limit if the Secretary decides that it is reasonable to do so. *See* 19 CFR § 351.213(d)(1). Hylsa, Mueller and Southland withdrew their respective requests for review within 90 days of the date of publication of the notice of initiation. No other party requested an administrative review for this period. Therefore, consistent with 19 CFR § 351.213(d)(1), the Department hereby rescinds the administrative review of the antidumping duty order on pipe and tube from Mexico for the period November 1, 2006, through October 31, 2007. The Department intends to issue assessment instructions to Customs and Border Protection 15 days after the date of publication of this rescission of administrative review.

This notice serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR § 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice is published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR § 351.213(d)(4).

Dated: February 4, 2008.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E8–2565 Filed 2–11–08; 8:45 am]

BILLING CODE 3510–DR–S

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Submission for OMB Review; Comment Request

The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: United States Patent and Trademark Office (USPTO), Department of Commerce.

Title: Patent Prosecution Highway (PPH) Pilot Program.

Form Number(s): PTO/SB/10, PTO/SB/20.

Agency Approval Number: 0651–0058.

Type of Request: Revision of a currently approved collection.

Burden: 1,575 hours annually.

Number of Respondents: 800 responses per year.

Avg. Hours Per Response: The USPTO estimates that it will take the public approximately 1.5 hours to gather the necessary information, prepare the form, and submit the completed Request for Participation in the New Route Pilot Program.

Needs and Uses: A work-sharing pilot program called the ''New Route'' is being established between the United States Patent and Trademark Office (USPTO) and the Japan Patent Office (JPO). Under the New Route, a filing in one member office of this arrangement would be deemed a filing in all member offices. The first office and applicant would be given a 30-month processing time frame in which to make available a first office action and any necessary translations to the second office(s), and the second office(s) would exploit the search and examination results of the first office in conducting their own examination. The information collection includes one proposed form, Request for Participation in the New Route Pilot Program Between the JPO and the USPTO (PTO/SB/10), which may be used by applicants to request participation in the pilot program and to ensure that they meet the program requirements. This form will be added to this collection.

Affected Public: Individuals or households; businesses or other for-profits; and not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by any of the following methods:

E-mail: Susan.Fawcett@uspto.gov. Include ''0651–0058 copy request'' in the subject line of the message.

Fax: 571–273–0112, marked to the attention of Susan Fawcett.

Mail: Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before March 13, 2008 to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, 725 17th Street, NW., Washington, DC 20503.

Dated: February 5, 2008.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer, Customer Information Services Group, Public Information Services Division.

[FR Doc. E8–2550 Filed 2–11–08; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–C–2008–0003]

National Medal of Technology and Innovation Nomination Evaluation Committee Meeting

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of closed meeting.

SUMMARY: The National Medal of Technology and Innovation (NMTI) Nomination Evaluation Committee will meet in closed session on Tuesday,

March 4, 2008. The primary purpose of the meeting is the discussion of relative merits of persons and companies nominated for the NMTI award.

DATES: The meeting will convene Tuesday, March 4, 2008, at 10 a.m. and adjourn at 4 p.m.

ADDRESSES: The meeting will be held at the United States Patent and Trademark Office, 600 Dulany Street, Alexandria, VA 22314.

FOR FURTHER INFORMATION CONTACT: Jennifer Lo, Program Manager, National Medal of Technology and Innovation Program, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450, telephone (571) 272–7640, or by electronic mail: *nmti@uspto.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. app. 2, notice is hereby given that the NMTI Nomination Evaluation Committee, United States Patent and Trademark Office, will meet at the United States Patent and Trademark Office campus in Alexandria, VA.

The NMTI Nomination Evaluation Committee was established in accordance with the provisions of the NMTI Nomination Evaluation Committee's charter and the Federal Advisory Committee Act. The NMTI Nomination Evaluation Committee meeting will be closed to the public in accordance with section 552b(c)(4), (6) and (9)(B) of Title 5, U.S.C. because it will involve discussion of relative merits of persons and companies nominated for the NMTI. Public disclosure of this information would likely frustrate implementation of the NMTI program because premature publicity about candidates under consideration for the NMTI award, who may or may not ultimately receive the award, would be likely to discourage nominations for the award. The Secretary of Commerce is responsible for recommending to the President prospective NMTI recipients. The NMTI Nomination Evaluation Committee makes its recommendations for the NMTI candidates to the Secretary of Commerce, who in turn makes recommendations to the President for final selection. NMTI Nomination Evaluation Committee members are drawn from both the public and private sectors and are appointed by the Secretary for three-year terms, with eligibility for one reappointment. The NMTI Nomination Evaluation Committee members are composed of distinguished experts in the fields of science, technology, business and patent law. The General Counsel formally determined on January 18, 2008, pursuant to section 10(d) of the Federal Advisory Committee Act, that the meeting may be closed because Committee members are concerned with matters that are within the purview of 5 U.S.C. 552b(c)(4), (6) and (9)(B). Due to closure of the meeting, copies of the minutes of the meeting will not be available. A copy of the determination is available for public inspection at the United States Patent and Trademark Office.

Dated: February 5, 2008.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. E8–2511 Filed 2–11–08; 8:45 am]

BILLING CODE 3510–16–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter the ''Corporation''), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, the Corporation is soliciting comments concerning the development of its Disaster Response Cooperative Agreement applications. These applications are used by current grantees to participate in FEMA Mission Assigned disaster activities and receive reimbursement for expenses accrued while on assignment.

Copies of the information collection requests can be obtained by contacting the office listed in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by April 14, 2008.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) *By mail sent to:* Corporation for National and Community Service, Office of Emergency Management; Attention: Phil Shaw, Emergency Management Coordinator, 1201 New York Avenue, NW., 9th Floor, Washington, DC 20525.

(2) By hand delivery or by courier to the Corporation's mailroom at Room 8100 at the mail address given in paragraph (1) above, between 9 a.m. and 4 p.m. Monday through Friday, except Federal holidays.

(3) *By fax to:* (202) 606–3477, Attention Phil Shaw, Emergency Management Coordinator.

(4) Electronically through the Corporation's e-mail address system: *pshaw@cns.gov.*

FOR FURTHER INFORMATION CONTACT: Phil Shaw, (202) 606–6697, or by e-mail at *pshaw@cns.gov.*

SUPPLEMENTARY INFORMATION: The Corporation is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Background

The Disaster Response Cooperative Agreement allows an existing Corporation grantee to establish a legal framework with the Corporation to support disaster response activities assigned by a FEMA Mission Assignment. Programs operating under a Cooperative Agreement can receive reimbursement of expenses accrued while on disaster assignment.

Current Action

The Corporation seeks to develop a new Disaster Response Cooperative Agreement (DRCA) Application. When

developed, the application will revise/clarify the application review and clearance process. It will also expand data collection to support enhanced asset mapping efforts.

Currently, DRCAs are solicited through the SF–424 Application for Federal Assistance. The Corporation also seeks to continue using the current application until the new application is approved by OMB. The current application is due to expire on August 31, 2008.

Type of Review: New Collection.

Agency: Corporation for National and Community Service.

Title: Disaster Response Cooperative Agreement Application.

OMB Number: None.

Frequency: Annual.

Affected Public: Existing CNCS Grantees.

Number of Respondents: 100.

Estimated Time Per Respondent: Average 2 hours.

Total Burden Hours: 200 hours.

Total Burden Cost (capital/startup): None.

Total Annual Cost (operating/maintaining systems or purchasing services): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: February 4, 2008.

Merlene Mazyck,

*Director, AmeriCorps*NCCC.*

[FR Doc. E8–2473 Filed 2–11–08; 8:45 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

Department of the Navy

[USN–2008–0004]

Privacy Act of 1974; Systems of Records

AGENCY: Department of the Navy, Department of Defense.

ACTION: Notice To Alter a System of Records.

SUMMARY: The Department of Navy proposes to alter a system of records notice in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), amended. The alteration adds three new routine uses and expands the categories of records collected.

DATES: This action will be effective without further notice on March 13, 2008 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Mrs. Doris Lama, Department of the Navy, 2000 Navy Pentagon, Washington, DC 20350–2000.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on February 5, 2008, to the House Committee on Government Oversight and Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

February 6, 2008.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

NM01700–1

SYSTEM NAME:

DON General Morale, Welfare, and Recreation Records (June 14, 2006, 71 FR 34321).

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete *http://neds.daps.dla.mil/sndl.htm* and replace with *http://doni.daps.dla.mil/sndl.aspx.*

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

After the words ''insurance information;'' add ''credit cards and other records of payments;''

Add second paragraph ''Activities that follow the American College of Sports Medicine Rules and Guidelines collect additional information, such as medical history, medications being taken, injury status, and who to contact in case of emergency.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; 26 U.S.C. 6041; BUPERS Instruction 1710.11C, Operations of Morale, Welfare and Recreation Programs 2003; MCOP 1700.27, Marine Corps, Morale, Welfare and Recreation Policy Manual, Ch 1; NAVSO P–3520, Financial Management Policies and Procedures for Morale, Welfare and Recreation Programs; and E.O. 9397 (SSN).''

PURPOSE(S):

Delete para 2.

Add new paras ''To provide a means of paying, recording, accounting, reporting, and controlling expenditures and merchandise inventories associated with MWR programs, activities, and events to include raffles, Monte Carlo, bingo prizes, and gaming machines.

To enable fitness/sports facility personnel to determine the appropriate level of activity participation.

To provide on-base emergency personnel with medical information regarding the emergency.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

ADD THE FOLLOWING THREE ROUTINE USES TO THIS SECTION:

''To the media or for public release to publicize the names and photographs of participants in league or other activities and events for marketing or other similar purposes.

To credit card processors, banks, and other financial institutions to process payments made by credit or debit cards, by check, or other payment methods.

To provide health and personal information to an off-base medical treatment facility should a member be taken there for treatment.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Delete entry and replace with ''Paper records in file folders and networked data bases.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Policy Officials: For Navy activities—Commander, Navy Installations Command (N–94), 5720 Integrity Drive, Millington, TN 38055–6500; For Marine Corps activities—Commandant of the Marine Corps, Personal and Family Readiness Division (MRX), 3044 Catlin Avenue, Quantico, VA 22134–5099.''

RECORD HOLDERS:

Commanding officer of the activity in question. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://doni.daps.dla.mil/sndl.aspx.*

NOTIFICATION PROCEDURE:

In entry delete *http://neds.daps.dla.mil/sndl.htm* and replace with *http://doni.daps.dla.mil/sndl.aspx.*

RECORD ACCESS PROCEDURES:

In entry delete *http://neds.daps.dla.mil/sndl.htm* and replace with *http://doni.daps.dla.mil/sndl.aspx.*

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''Individual or group receiving the MWR services to include but not limited to Monte Carlo, others who operate MWR programs, classes, events, and companies.''

* * * * *

NM01700–1

SYSTEM NAME:

DON General Morale, Welfare, and Recreation Records.

SYSTEM LOCATION:

Organizational elements of the Department of the Navy. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://doni.daps.dla.mil/sndl.aspx.*

Commander, U.S. Joint Forces Command, 1562 Mitscher Avenue, Suite 200, Norfolk, VA 23551–2488.

Commander, U.S. Pacific Command, P.O. Box 64028, Camp H.M. Smith, HI 96861–4028.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Personnel authorized to use DON-sponsored Morale, Welfare, Recreation (MWR) services, youth services, athletic and recreational services, Armed Forces Recreation Centers, DON recreation machines, and/or to participate in MWR-type activities, to include: bingo games; professional entertainment groups recognized by the Armed Forces Entertainment; DON athletic team members; ticket holders of athletic events; and units of national youth groups such as Boy Scouts, Girl Scouts, and 4–H Clubs.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name; branch of service; home and duty station addresses; home, business, and cell telephone numbers; military/civilian status; Social Security Number; Unit Identification Code (UIC); travel orders/vouchers; security check results; command contact person; boat and mooring storage agreement; insurance information; credit cards and other records of payments; contact address; contract, waiver, release, and indemnification agreements; check out and control sheets; bingo pay-out control sheet indicating individual name, grade, Social Security Number, duty station, dates and amount of bingo winnings paid; and Internal Revenue Forms W2–G and 5754, (Gambling Winnings and Statement by Person(s) Receiving Gambling Winnings, respectively).

Activities that follow the American College of Sports Medicine Rules and Guidelines collect additional information, such as medical history, medications being taken, injury status, and who to contact in case of emergency.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; 26 U.S.C. 6041; BUPERS Instruction 1710.11C, Operations of Morale, Welfare and Recreation Programs 2003; MCOP 1700.27, Marine Corps, Morale, Welfare and Recreation Policy Manual, Ch 1; NAVSO P–3520, Financial Management Policies and Procedures for Morale, Welfare and Recreation Programs; and E.O. 9397 (SSN).

PURPOSE(S):

To administer programs devoted to the mental and physical well-being of DON personnel and other authorized users; to document the approval and conduct of specific contests, shows, entertainment programs, sports activities/competitions, and other MWR-type activities and events sponsored or sanctioned by the DON.

To provide a means of paying, recording, accounting, reporting, and controlling expenditures and merchandise inventories associated with MWR programs, activities, and events to include raffles, Monte Carlo, bingo prizes, and gaming machines.

To enable fitness/sports facility personnel to determine the appropriate level of activity participation.

To provide on-base emergency personnel with medical information regarding the emergency.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the media or for public release to publicize the names and photographs of participants in league or other activities and events for marketing or other similar purposes.

To credit card processors, banks, and other financial institutions to process payments made by credit or debit cards, by check, or other payment methods.

To provide health and personal information to an off-base medical treatment facility should a member be taken there for treatment.

To the Internal Revenue Service to report all monies and items of merchandise paid to winners of games whose one-time winnings are $1,200 or more.

The DoD 'Blanket Routine Uses' set forth at the beginning of the Navy's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and networked data bases.

RETRIEVABILITY:

Name and Social Security Number of patron.

SAFEGUARDS:

Password controlled system, file, and element access based on predefined need-to-know. Physical access to terminals, terminal rooms, buildings and activities' grounds are controlled by locked terminals and rooms, guards, personnel screening and visitor registers.

RETENTION AND DISPOSAL:

Bingo records are maintained on-site for four years and then shipped to a Federal Records Center for storage for an additional three years. After seven years, records are destroyed.

All other documents are destroyed after 2 years, unless required for current operation.

SYSTEM MANAGER(S) AND ADDRESS:

Policy Officials: For Navy activities—Commander, Navy Installations Command (N–94), 5720 Integrity Drive, Millington, TN 38055–6500; For Marine Corps activities—Commandant of the Marine Corps, Personal and Family Readiness Division (MRX), 3044 Catlin Avenue, Quantico, VA 22134–5099.

Record Holders: Commanding officer of the activity in question. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://doni.daps.dla.mil/sndl.aspx.*

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the

commanding officer of the activity in question. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://doni.daps.dla.mil/sndl.aspx.*

The request should include full name, Social Security Number (SSN), address of the individual concerned and be signed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the commanding officer of the activity in question. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://doni.daps.dla.mil/sndl.aspx.*

The request should include full name, Social Security Number (SSN), address of the individual concerned, and be signed.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual or group receiving the MWR services to include but not limited to Monte Carlo, others who operate MWR programs, classes, events, and companies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E8–2537 Filed 2–11–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before April 14, 2008.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: February 6, 2008.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Elementary and Secondary Education

Type of Review: Revision.

Title: Binational Migrant Education Program (BMEP) State MEP Director Survey.

Frequency: Annually.

Affected Public: Federal Government; State, Local or Tribal Govt', SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 833. *Burden Hours:* 417.

Abstract: The U.S. Department of Education (ED) and its Office of Migrant Education (OME) is requesting clearance of a survey of State Directors of the Migrant Education Program (MEP) regarding a survey intended to collect additional data on the binational migrant student population. The collection of information is necessary due to the following circumstances: The State MEPs need a better understanding of key demographics as well as a better understanding of the special educational needs of the binational migrant student population. The Binational Migrant Education Program (BMEP) is an effort to support the coordination of activities among U.S. States that participate in programs in Mexican States to improve the continuity of educational and educationally-related support services for migrant students who migrate between the two countries.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 3587. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E8–2530 Filed 2–11–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2232]

Duke Energy Corporation; Notice of Availability of Environmental Assessment

February 6, 2008.

In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Energy Regulatory Commission's (Commission) regulations (18 CFR Part 380), Commission staff has reviewed plans, filed May 16, 2007, to perform embankment seismic stability improvement work at Catawba Dam, part of the Catawba-Wateree Project's Bridgewater Development, which is located on the Catawba River in McDowell and Burke counties, North

Carolina. The project occupies nine counties in North Carolina and five counties in South Carolina.

The project licensee, Duke Energy Corporation (Duke Power), plans to add an earthfill berm to the downstream side of the embankment of Catawba Dam because it has been determined that the dam could fail during a seismic event. Accordingly, the Commission required remediation under Part 12 of its regulations. In the environmental assessment (EA), Commission staff has analyzed the probable environmental effects of the proposed work and has concluded that approval, with appropriate environmental measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

A copy of the EA is available for review at the Commission's Public Reference Room, or it may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''elibrary'' link. Enter the docket number (P–2232) in the docket number field to access the document. For assistance, call (202) 502–8222, or (202) 502–8659 (for TTY).

Kimberly D. Bose,

Secretary.

[FR Doc. E8–2527 Filed 2–11–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

February 7, 2008.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP96–312–178.

Applicants: Tennessee Gas Pipeline Company.

Description: Tennessee Gas Pipeline Co. submits Gas Transportation Agreement with Statoil Natural Gas, LLC pursuant to its Rate Schedule FT–A etc.

Filed Date: 02/05/2008.

Accession Number: 20080206–0233.

Comment Date: 5 p.m. Eastern Time on Tuesday, February 19, 2008.

Docket Numbers: RP99–301–200.

Applicants: ANR Pipeline Company.

Description: ANR Pipeline Company submits an amendment to Rate Schedule FTS–1 Negotiated Rate Agreement between ANR and Centerpoint Energy Services, Inc.

Filed Date: 02/01/2008.

Accession Number: 20080205–0278.

Comment Date: 5 p.m. Eastern Time on Wednesday, February 13, 2008.

Docket Numbers: RP06–298–006.

Applicants: National Fuel Gas Supply Corporation.

Description: National Fuel Gas Supply Corporation submits its Semi-Annual Report of Operational Sales of Gas pursuant to Section 40–3 of the General Terms and Conditions of its FERC Gas Tariff.

Filed Date: 02/01/2008.

Accession Number: 20080205–0276.

Comment Date: 5 p.m. Eastern Time on Wednesday, February 13, 2008.

Docket Numbers: RP07–114–002.

Applicants: Cheyenne Plains Gas Pipeline Company LLC.

Description: Cheyenne Plains Gas Pipeline Company, LLC submits Original Volume 1, First Revised Sheet 28 and 28A of its FERC Gas Tariff.

Filed Date: 02/01/2008.

Accession Number: 20080205–0277.

Comment Date: 5 p.m. Eastern Time on Wednesday, February 13, 2008.

Docket Numbers: RP07–310–001.

Applicants: Mojave Pipeline Company.

Description: Mojave Pipeline Company submits First Revised Sheet 1 *et al.* to FERC Gas Tariff, Second Revised Volume 1, with proposed effective dates of February 1, 2008 and March 1, 2008.

Filed Date: 02/05/2008.

Accession Number: 20080206–0232.

Comment Date: 5 p.m. Eastern Time on Tuesday, February 19, 2008.

Docket Numbers: RP08–112–001.

Applicants: Sabine Pipe Line LLC.

Description: Sabine Pipe Line LLC submits Tenth Revised Sheet 20 of its FERC Gas Tariff Volume 1, tariff sheet proposed to become effective March 1, 2008.

Filed Date: 02/04/2008.

Accession Number: 20080205–0300.

Comment Date: 5 p.m. Eastern Time on Tuesday, February 19, 2008.

Docket Numbers: RP08–131–001.

Applicants: Eastern Shore Natural Gas Company.

Description: Eastern Shore Natural Gas Company submits compliance filing to reflect the restoration of missing text to Eastern Shore's General Terms and Conditions Section 31 etc.

Filed Date: 02/04/2008.

Accession Number: 20080205–0275.

Comment Date: 5 p.m. Eastern Time on Tuesday, February 19, 2008.

Docket Numbers: RP08–144–001.

Applicants: Gulf States Transmission Corporation.

Description: Gulf States Transmission Corporation submits Fourth Revised Sheet 5 to be effective March 1, 2008.

Filed Date: 02/04/2008.

Accession Number: 20080205–0299.

Comment Date: 5 p.m. Eastern Time on Tuesday, February 19, 2008.

Docket Numbers: RP08–184–000.

Applicants: SG Resources Mississippi, L.L.C.

Description: SG Resources Mississippi, LLC submits Original Sheet 0 *et al.* to FERC Gas Tariff, Original Volume 1 etc.

Filed Date: 01/31/2008.

Accession Number: 20080205–0280.

Comment Date: 5 p.m. Eastern Time on Tuesday, February 12, 2008.

Docket Numbers: RP08–185–000.

Applicants: Texas Eastern Transmission LP.

Description: Texas Eastern Transmission, LP submits First Revised Sheet 223 and 258 of its FERC Gas Tariff, Revised Volume 2, to be effective February 1, 2008.

Filed Date: 02/01/2008.

Accession Number: 20080205–0296.

Comment Date: 5 p.m. Eastern Time on Wednesday, February 13, 2008.

Docket Numbers: RP08–186–000.

Applicants: National Fuel Gas Supply Corporation.

Description: Natural Fuel Gas Supply Corporation submits 111th Revised Sheet 9 to its FERC Gas Tariff, Fourth Revised Volume 1, proposed to be effective February 1, 2008.

Filed Date: 02/01/2008.

Accession Number: 20080205–0297.

Comment Date: 5 p.m. Eastern Time on Wednesday, February 13, 2008.

Docket Numbers: RP08–187–000.

Applicants: Northern Natural Gas Company.

Description: Northern Natural Gas Company submits 76 Revised Sheet 50 *et al.* to FERC Gas Tariff, Fifth Revised Volume 1, to become effective April 1, 2008.

Filed Date: 02/01/2008.

Accession Number: 20080205–0298.

Comment Date: 5 p.m. Eastern Time on Wednesday, February 13, 2008.

Docket Numbers: RP08–188–000.

Applicants: Egan Hub Storage, LLC.

Description: Egan Hub Storage, LLC submits Third Revised Sheet 4 *et al.* to its FERC Gas Tariff, First Revised Volume 2, to become effective March 6, 2008.

Filed Date: 02/04/2008.

Accession Number: 20080205–0279.

Comment Date: 5 p.m. Eastern Time on Tuesday, February 19, 2008.

Docket Numbers: CP93–618–018.

Applicants: Gas Transmission Northwest Corporation.

Descriptions: Gas Transmission Northwest Corporation submits its Annual Report on Deferred Revenue Recovery Mechanism and Revenue

Reconciliation for the Year Ending October 31, 2007.

Filed Date: 01/31/2008.

Accession Number: 20080205–0311.

Comment Date: 5 p.m. Eastern Time on Tuesday, February 19, 2008.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*. or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E8–2544 Filed 2–11–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TS08–2–000]

FPL Energy Oliver Wind, LLC; Notice of Filing

February 6, 2008.

Take notice that on January 30, 2008, FPL Energy Oliver Wind, LLC filed a petition for waiver of certain Standards of Conduct regulations, pursuant to the Commission's Order Nos. 888, 889, and 890.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on February 20, 2008.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–2528 Filed 2–11–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TS08–3–000]

Peetz Table Wind Energy, LLC; Notice of Filing

February 6, 2008.

Take notice that on January 30, 2008, Peetz Table Wind Energy, LLC filed a petition for waiver of certain Standards of Conduct regulations, pursuant to the Commission's Order Nos. 888, 889, and 890.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on February 20, 2008.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–2526 Filed 2–11–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–67–000]

Tennessee Gas Pipeline Company; Notice of Request Under Blanket Authorization

February 6, 2008.

Take notice that on February 1, 2008, Tennessee Gas Pipeline Company (Tennessee), 1001 Louisiana, Houston, Texas 77002, filed in Docket No. CP08–67–000, a prior notice request pursuant to sections 157.205 and 157.212 of the Federal Energy Regulatory Commission's regulations under the Natural Gas Act for authorization to construct, own, and operate an interconnection with Golden Pass Pipeline LLC (Golden Pass), located in Calcasieu Parish, Louisiana, all as more fully set forth in the application, which is on file with the Commission and open to public inspection. The filing may also be viewed on the Web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Specifically, Tennessee proposes to establish a new interconnection with Golden Pass on Tennessee's pipeline designated as Line 800–1 at an existing side valve in Calcasieu Parish, Louisiana. Tennessee proposes to install a twenty-four inch flanged tee, as well as appurtenances constructed pursuant to section 2.55(a), including a ball valve, check valve, electronic gas measurement, chromatograph with sensing elements, communications for SCADA, and an 8 x 10 building. Tennessee estimates the cost of the interconnection facilities to be $387,000, for which Tennessee will be fully reimbursed by Golden Pass. Tennessee states that the interconnection will allow Golden Pass to deliver and Tennessee to receive up to 600 MMcf/day.

Any questions regarding the application should be directed to Jay V. Allen, Senior Counsel, Tennessee Gas Pipeline Company, 1001 Louisiana, Houston, Texas 77002, call (713) 420–5589 or fax (713) 420–1601, or Debbie Kalisek, Analyst, Certificates & Regulatory Compliance, call (713) 420–3292 or fax (713) 420–1605.

Any person or the Commission's Staff may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and, pursuant to section 157.205 of the Commission's Regulations under the Natural Gas Act (NGA) (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–2529 Filed 2–11–08; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2008–0067, FRL–8527–7]

Agency Information Collection Activities: Proposed Collection; Comment Request; Technology Performance and Product Information To Support Vendor Information Summaries (Renewal), EPA ICR Number 2154.03, OMB Control Number 2050–0194

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB). This is a request to renew an existing approved collection. This ICR is scheduled to expire on May 31, 2008. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before April 14, 2008.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–ORD–2008–0067, by one of the following methods:

- *http://www.regulations.gov:* (Our preferred method) Follow the on-line instructions for submitting comments.
- *E-mail: ord.docket@epa.gov.*
- *Fax:* 202–566–9744.
- *Mail:* Office of Research & Development Docket, Environmental Protection Agency, Mail Code: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- *Hand Delivery:* EPA Docket Center, Public Reading Room, EPA West Building, Room 3334, 1301 Constitution Avenue, NW., Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–ORD–2008–0067. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

FOR FURTHER INFORMATION CONTACT: Shannon D. Serre, Environmental Protection Agency, 109 T.W. Alexander

Drive, E343–06, Research Triangle Park, NC 27711; telephone number: 919–541–3817; fax number: 919–541–0496; e-mail address: *serre.shannon@epa.gov.*

SUPPLEMENTARY INFORMATION:

How Can I Access the Docket and/or Submit Comments?

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–ORD–2008–0067, which is available for online viewing at *http://www.regulations.gov,* or in person viewing at the ORD Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202–566–1744, and the telephone number for the ORD Docket is 202–566–1752.

Use *http://www.regulations.gov* to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified in this document.

What Information Is EPA Particularly Interested In?

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits comments and information to enable it to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) enhance the quality, utility, and clarity of the information to be collected; and

(iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

What Should I Consider When I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Offer alternative ways to improve the collection activity.

6. Make sure to submit your comments by the deadline identified under **DATES.**

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

What Information Collection Activity or ICR Does This Apply To?

Affected entities: Entities potentially affected by this action are vendors and developers of technologies (commercially available and those under development) that are intended to be used to decontaminate structures (e.g., buildings (interior and exterior) and water distribution systems) contaminated with chemical, biological, or radiological materials and technologies for use in detecting, measuring, and monitoring these same materials in air, on surfaces, and in water.

Title: Technology Performance and Product Information To Support Vendor Information Summaries (Renewal).

ICR numbers: EPA ICR No. 2154.03 OMB Control No. 2050–0194.

ICR status: This ICR is currently scheduled to expire on May 31, 2008. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The U.S. EPA Office of Research and Development's National Homeland Security Research Center (NHSRC) is helping to protect human health and the environment from adverse impacts resulting from intentional acts of terror. With an emphasis on decontamination and consequence management, water infrastructure protection, and threat and consequence assessment, NHSRC scientists and engineers are working to develop tools and information that will help detect the intentional introduction of chemical, biological, and radiological contaminants in buildings or water systems, the containment of these contaminants, the decontamination of buildings and/or water systems, and the disposal of material resulting from cleanups.

An important facet of the NHSRC mission is identifying, testing, and evaluating technologies to support emergency response personnel, consequence managers, decision-makers, and government officials. EPA has initiated this effort to develop brief vendor information summaries of available technologies relevant to the detection and decontamination of drinking water systems, building materials, building structures, and indoor air that may become contaminated with chemical, biological, or radiological contaminants. These summaries will be based upon vendor-generated or -provided information including any independent, validated test data generated by governmental or other organizations and provided to EPA through this ICR. Information provided will be used to produce 4–10 page summaries on each of the technologies for which vendors voluntarily agreed to submit the requested information. These summaries will be shared with EPA and other emergency response personnel, building and facility managers, and water utility operators. The information provided by technology developers and vendors will also be used by the NHSRC's Technology Testing and Evaluation Program (TTEP) to identify technologies that may be suitable candidates for testing and evaluation and to track those technologies under development that may eventually be ready for rigorous testing and evaluation.

The submission of information is voluntary. Because the summarized information will be publicly available, technology vendors/developers will be discouraged from submitting CBI. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it

displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 15 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR provides a detailed explanation of the Agency's estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 70.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 1050 hours.

Estimated total annual costs: $82,460. This includes an estimated burden cost of $82,040 and an estimated cost of $420 for capital investment or maintenance and operational costs.

What Is the Next Step in the Process for This ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: January 24, 2008.

Jonathan G. Herrmann,

Director, National Homeland Security Research Center.

[FR Doc. E8–2542 Filed 2–11–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2007–0272; FRL–8527–8]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Correction of Misreported Chemical Substances on the TSCA Inventory; EPA ICR No. 1741.05, OMB No. 2070–0145

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Correction of Misreported Chemical Substances on the TSCA Inventory; EPA ICR No. 1741.05, OMB No. 2070–0145. The ICR, which is abstracted below, describes the nature of the information collection activity and its expected burden and costs.

DATES: Additional comments may be submitted on or before March 13, 2008.

ADDRESSES: Submit your comments, referencing docket ID Number EPA–HQ–OPPT–2007–0272 to (1) EPA online using *http://www.regulations.gov* (our preferred method), by e-mail to *oppt.ncic@epa.gov* or by mail to: Document Control Office (DCO), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, Mail Code: 7407T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Barbara Cunningham, Director, Environmental Assistance Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, Mailcode: 7408–M, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202–554–1404; e-mail address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On September 21, 2007 (72 FR 54034), EPA sought comments on this renewal ICR. EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments during the comment period. Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OPPT–2007–0272, which is available for online viewing at *http://www.regulations.gov,* or in person inspection at the OPPT Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202–566–1744, and the telephone number for the Pollution Prevention and Toxics Docket is 202–566–0280. Use *http://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in *http://www.regulations.gov.* The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in *http://www.regulations.gov.* For further information about the electronic docket, go to *http://www.regulations.gov.*

Title: Correction of Misreported Chemical Substances on the TSCA Inventory.

ICR Status: This ICR is currently scheduled to expire on February 29, 2008. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are

listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Section 8(b) of TSCA requires EPA to compile and keep current an Inventory of Chemical Substances in Commerce, which is a listing of chemical substances manufactured, imported, and processed for commercial purposes in the United States. The purpose of the Inventory is to define, for the purpose of TSCA, what chemical substances exist in U.S. commerce. Since the Inventory thereby performs a regulatory function by distinguishing between existing chemicals and new chemicals, which TSCA regulates in different ways, it is imperative that the Inventory be accurate.

However, from time to time, EPA or respondents discover that substances have been incorrectly described by reporting companies. Reported substances have been unintentionally misidentified as a result of simple typographical errors, the misidentification of substances, or the lack of sufficient technical or analytical capabilities to characterize fully the exact chemical substances. EPA has developed guidelines (45 FR 50544, July 29, 1980) under which incorrectly described substances listed in the Inventory can be corrected. The correction mechanism ensures the accuracy of the Inventory without imposing an unreasonable burden on the chemical industry. Without the Inventory correction mechanism, a company that submitted incorrect information would have to file a premanufacture notification (PMN) under TSCA section 5 to place the correct chemical substance on the Inventory whenever the previously reported substance is found to be misidentified. This would impose a much greater burden on both EPA and the submitter than the existing correction mechanism. This information collection applies to reporting and recordkeeping activities associated with the correction of misreported chemical substances found on the TSCA Inventory.

Responses to the collection of information are voluntary. Respondents may claim all or part of a notice as CBI. EPA will disclose information that is covered by a CBI claim only to the extent permitted by, and in accordance with, the procedures in 40 CFR part 2.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to be 2.25 hours per response. Burden means the total time, effort or financial resources expended by persons to generate, maintain, retain or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install and utilize technology and systems for the purposes of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Entities potentially affected by this action are manufacturers or importers of chemical substances, mixtures or categories listed on the TSCA Inventory and regulated under TSCA section 8, who had reported to the initial effort to establish the TSCA Inventory in 1979, and who need to make a correction to that submission.

Frequency of Collection: On occasion.

Estimated average number of responses for each respondent: 1.

Estimated No. of Respondents: 9.

Estimated Total Annual Burden on Respondents: 20 hours.

Estimated Total Annual Costs: $1,061.

Changes in Burden Estimates: There is no net change in the total estimated respondent burden compared with that currently in the OMB inventory.

Dated: February 5, 2008.

Sara Hisel-McCoy,

Director, Collection Strategies Division.

[FR Doc. E8–2543 Filed 2–11–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8527–9]

The Sixteenth Meeting of the Mississippi River/Gulf of Mexico Watershed Nutrient Task Force

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; meeting announcement.

SUMMARY: This notice announces the Sixteenth Public Meeting of the Mississippi River/Gulf of Mexico Watershed Nutrient Task Force. The purpose of this Task Force, consisting of federal and state members, is to lead efforts to coordinate and support nutrient management and hypoxia-related activities in the Mississippi River and Gulf of Mexico watersheds. The matter for discussion at the meeting is to seek approval on the revised 2001 Action Plan for Reducing, Mitigating, and Controlling Hypoxia in the Northern Gulf of Mexico for release in March 2008. The public will be afforded an opportunity to provide input to the Task Force during open discussion periods.

DATES: The public meeting will be held on February 28, 2008, from 1–5 p.m. CST.

ADDRESSES: The meeting is located at Intercontinental Chicago, 505 N. Michigan Ave., Chicago, IL 60611. Telephone: (312) 321–8706. Additional information, meeting materials and meeting registration can be found at *http://www.epa.gov/msbasin.*

FOR FURTHER INFORMATION CONTACT: For registration and other information contact Kristen Goodrich, U.S. EPA, Oceans and Coastal Protection Division (OCPD), Mail Code 4504T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; Phone (202) 566–1284; E-mail: *OW-hypoxia@epa.gov.*

Dated: February 6, 2008.

Craig Hooks,

Director, Office of Wetlands, Oceans and Watersheds.

[FR Doc. E8–2545 Filed 2–11–08; 8:45 am]

BILLING CODE 6560–50–P

COUNCIL ON ENVIRONMENTAL QUALITY

The National Environmental Policy Act

AGENCY: Council on Environmental Quality.

ACTION: Notice of Availability, ''A Citizen's Guide to the National

Environmental Policy Act—Having Your Voice Heard.''

SUMMARY: The Council on Environmental Quality (CEQ) has published ''A Citizen's Guide to the NEPA—Having Your Voice Heard.'' The guide explains the National Environmental Policy Act (NEPA), and how it is implemented, as well as how people outside the Federal government—individual citizens, private sector permit applicants, members of organized groups, and representatives of Tribal, State, or local governments—can better participate in the Federal environmental impact assessment process. This informational guide contains no new requirements.

ADDRESSES: Electronic or facsimile requests are preferred given that Federal agencies often experience mail delays as a result of security screening. Submit requests for the guide via electronic mail to *hgreczmiel@ceq.eop.gov* with the subject line ''NEPA Citizen's Guide.'' Fax requests to ''NEPA Citizen's Guide'' at (202) 456–0753. Mail requests to NEPA Citizen's Guide, Attn.: Associate Director for NEPA Oversight, 722 Jackson Place, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Horst Greczmiel at (202) 395–5750.

SUPPLEMENTARY INFORMATION: CEQ established a NEPA task force and is implementing its recommendations to modernize the implementation of NEPA and make the NEPA process more effective and efficient. This guide responds to public requests and comments received during the development of the ''National Environmental Policy Act Task Force Report to the CEQ—Modernizing NEPA Implementation,'' and from participants in the four NEPA Regional Roundtables that reviewed the report. More information about the task force is posted at *http://ceq.eh.doe.gov/ntf*. CEQ requested public comments on the proposed guide on February 21, 2007, 72 FR 7876. Those comments are posted at *http://ceq.eh.doe.gov/ntf/implementation.html*.

The ''A Citizen's Guide to the NEPA—Having Your Voice Heard'' describes the NEPA process and suggests ways in which citizens and non-Federal entities can participate in Federal agencies' implementation of NEPA. The final guide, revised in response to public comments, includes a discussion of the environmental policies set out in section 101 of NEPA, clarifying specific points in the process when public comments and input are effective, explaining variations in planning processes for Federal highways, and distinguishing between required and optional implementation.

The procedural steps in analyzing proposed Federal actions through the three levels of analysis provided in the CEQ Regulations Implementing the Procedural Requirements of the National Environmental Policy Act (40 CFR parts 1500–1508)—the categorical exclusion, the environmental assessment, and the environmental impact statement—are described. The guide also advises how to obtain assistance from CEQ and other government agencies, in addition to available options to those concerned whether an agency is properly implementing its NEPA responsibilities.

Dated: February 4, 2008.

James L. Connaughton,

Chairman, Council on Environmental Quality.

[FR Doc. E8–2554 Filed 2–11–08; 8:45 am]

BILLING CODE 3125–W8–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Sunshine Act Meeting

DATE AND TIME: Tuesday, February 19, 2008, 10:30 a.m. Eastern Time.

PLACE: Clarence M. Mitchell, Jr. Conference Room on the Ninth Floor of the EEOC Office Building, 1801 ''L'' Street, NW., Washington, DC 20507.

STATUS: The meeting will be open to the public.

MATTERS TO BE CONSIDERED: Open Session:

1. Announcement of Notation Votes, and

2. Obligation of Funds for a Temporary Interactive Voice Response/Automatic Call Distribution (IVR/ACD) Non-competitive Hosting Contract and a Competitive Contract for Technology Support of Customer Response Function.

Note: In accordance with the Sunshine Act, the meeting will be open to public observation of the Commission's deliberations and voting. (In addition to publishing notices on EEOC Commission meetings in the **Federal Register**, the Commission also provides a recorded announcement a full week in advance on future Commission sessions.)

Please telephone (202) 663–7100 (voice) and (202) 663–4074 (TTY) at any time for information on these meetings. The EEOC provides sign language interpretation at Commission meetings for the hearing impaired. Requests for other reasonable accommodations may be made by using the voice and TTYnumbers listed above. *Contact Person for More Information:* Stephen Llewellyn, Executive Officer on (202) 663–4070.

Dated: February 8, 2008.

Stephen Llewellyn,

Executive Officer, Executive Secretary.

[FR Doc. 08–653 Filed 2–8–08; 1:43 pm]

BILLING CODE 6570–01–M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to OMB for Review and Approval, Comments Requested

February 6, 2008.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden, invites the general public and other federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before March 13, 2008. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via Internet at *Nicholas_A._Fraser@omb.eop.gov* or via fax at (202) 395–5167 and to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th

Street, SW., Washington, DC or via Internet at *Cathy.Williams@fcc.gov* or *PRA@fcc.gov.* To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB control number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams at (202) 418–2918, or via Internet at *Cathy.Williams@fcc.gov*.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0095.

Title: Multi-Channel Video Programming Distributors Annual Employment Report.

Form Number: FCC Form 395–A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; not-for-profit institutions.

Number of Respondents: 2,500.

Estimated Time per Response: 53 minutes.

Frequency of Response: Recordkeeping requirement; annual reporting requirement; once every five year reporting requirement.

Total Annual Burden: 2,200 hours.

Total Annual Cost: None.

Nature of Response: Required to obtain or retain benefits.

Confidentiality: Whether the Form is confidential will be determined in a pending Commission rulemaking.

Privacy Impact Assessment: No impact.

Needs and Uses: FCC Form 395–A, ''The Multi-Channel Video Programming Distributor Annual Employment Report,'' is a data collection device used by the Commission to assess industry employment trends and provide reports to Congress. By the Report, multichannel video programming distributors (''MVPDs'') identify employees by gender and race/ethnicity in fifteen specified job categories.

OMB Control Number: 3060–0390.

Title: Broadcast Station Annual Employment Report.

Form Number: FCC Form 395–B.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; not-for-profit institutions.

Number of Respondents: 14,000.

Estimated Time per Response: 53 minutes.

Frequency of Response: Annual reporting requirement.

Total Annual Burden: 12,320 hours.

Total Annual Cost: None.

Nature of Response: Required to obtain or retain benefits.

Confidentiality: Whether the Form is confidential will be determined in a pending Commission rulemaking.

Privacy Impact Assessment: No impact.

Needs and Uses: FCC Form 395–B, ''The Broadcast Station Annual Employment Report,'' is a data collection device used by the Commission to assess industry employment trends and provide reports to Congress. By the Report, broadcast licensees and permittees identify employees by gender and race/ethnicity in nine specified job categories.

Federal Communications Commission.

Ruth A. Dancey,

Associate Secretary.

[FR Doc. E8–2563 Filed 2–11–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:30 a.m., Tuesday, February 19, 2008.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Staff resource and work product planning.

3. Any items carried forward from a previously announced meeting.

FOR FURTHER INFORMATION CONTACT: Michelle Smith, Director, or Dave Skidmore, Assistant to the Board, Office of Board Members at 202–452–2955.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: February 8, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 08–655 Filed 2–8–08; 1:43 pm]

BILLING CODE 6210–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–08–08AP]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Youth Advice and Feedback to Inform Choose Respect Implementation (New)—National Center for Injury Prevention and Control (NCIPC),

Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NCIPC seeks to obtain, over a five year period, advice and feedback from tweens/teens (aged 11–14) regarding message development/placement, creative executions, appropriate partners, and other similar issues, to inform ongoing implementation and evaluation of the Choose Respect campaign (OMB#0920–0687 Expired 5/31/2006), an initiative intended to promote youth awareness of and participation in healthy peer relationships. Communication research indicates that campaign planning implementation must employ a consumer-oriented approach to ensure that program messages/materials, and their placement, can successfully gain the attention of and resonate with the intended audience. To that end, the NCIPC proposes conducting further planning, implementation, and evaluation research that enlists the involvement and support of youth, parents and other influencers and measures the effect of the campaign on the target audiences. The evaluation will provide interim and ongoing feedback to campaign planners regarding the implementation and progress of the campaign.

The proposed data collection will enlist geographically, culturally/racially/ethnically, and socio-economically diverse groups of young people to complete: (1) Ten minute online surveys, with 30 respondents, six times per year; and (2) 12 in-person focus groups, with 12 participants each, twice per year. Online surveys will reduce the potential burden for young people as web-based formats are convenient and consistent with the way they communicate and spend their leisure time and will involve a different group of 30 tweens/teens. In-person focus groups will involve different groups of young people and will be segmented by age and gender.

There are no costs to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (In hrs)	Total burden hours
Online survey: Boys and girls, aged 11–14	30	6	10/60	30
Focus group: Boys, aged 11–12, urban	12	2	1.5	36
Focus group: Boys, aged 11–12, suburban	12	2	1.5	36
Focus group: Girls, aged 11–12, urban	12	2	1.5	36
Focus group: Girls, aged 11–12, suburban	12	2	1.5	36
Focus group: Boys, aged 12–13, urban	12	2	1.5	36
Focus group: Girls, aged 12–13, suburban	12	2	1.5	36
Focus group: Boys, aged 12–13, suburban	12	2	1.5	36
Focus group: Girls, aged 12–13, urban	12	2	1.5	36
Focus group: Boys, aged 13–14, urban	12	2	1.5	36
Focus group: Boys, aged 13–14, suburban	12	2	1.5	36
Focus group: Girls, aged 13–14, urban	12	2	1.5	36
Focus group: Girls, aged 13–14, suburban	12	2	1.5	36
Totals	174	.....	.....	462

Dated: February 5, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–2508 Filed 2–11–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Task Force on Community Preventive Services

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Task Force on Community Preventive Services.

Times and Dates: 8 a.m.–6 p.m. EST, February 27, 2008. 8 a.m.–1 p.m EST, February 28, 2008.

Place: Centers for Disease Control and Prevention, 2500 Century Parkway, Atlanta, GA 30345.

Status: Open to the public, limited only by the space available.

Purpose: The mission of the Task Force is to develop and publish the Guide to Community Preventive Services (Community Guide), which consists of systematic reviews of the best available scientific evidence and associated recommendations regarding what works in the delivery of essential public health services.

Topics include: Reducing depression in older adults; increasing cancer screening; reducing sexual risk behavior (among adolescents); controlling obesity; and updating the Community Guide's vaccine-preventable diseases review.

Agenda items are subject to change as priorities dictate.

Persons interested in reserving a space for this meeting should call Tony Pearson-Clarke at 404. 498.0972 by close of business on February 19, 2008.

Contact person for additional information: Tony Pearson-Clarke, Community Guide Branch, Coordinating Center for Health Information and Service, National Center for Health Marking, Division of Health Communication and Marketing, Centers for Disease Control and Prevention, 1600 Clifton Road, M/S E–69, Atlanta, GA 30333, telephone: 404.498.0972.

Dated: January 31, 2008.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–2548 Filed 2–11–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 18, 2008, from 8:30 a.m. to 5 p.m. and on March 19, 2008, from 8:30 a.m. to 12:30 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Mimi Phan, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *mimi.phan@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On March 18, 2008, the committee will: (1) Discuss and provide comments on three new topics of this meeting; first new topic: The new clinical pharmacogenomics (PGx) concept paper. Key issues in the concept paper include an industry survey on the collection of PGx samples, and the applications of PGx in clinical development will be presented and (2) discuss and provide comments on the second new topic: Quantitative clinical pharmacology: Critical path opportunities. An example of a disease model and its applications will be presented. The regulatory experience, designs, and implications of pediatric studies will be discussed. On March 19, 2008, the committee will consider the third new topic: Renal impairment concept paper. The effects of renal impairment on Cytochrom P (CYP)/transporter, methods of evaluation of renal function, and the effects of hemodialysis on drug clearance will be discussed.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 4, 2008. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. each day. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 27, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 28, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Mimi Phan at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 4, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–2540 Filed 2–11–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2008–0075]

Commercial Fishing Industry Vessel Safety Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of Open Teleconference Meeting.

SUMMARY: This notice announces a teleconference of the Commercial Fishing Industry Vessel Safety Advisory Committee (CFIVSAC). The purpose of the teleconference is for CFIVSAC to discuss and prepare recommendations for the Coast Guard concerning the work of the Communications Subcommittee and the Risk Management Subcommittee and to discuss other CFIVSAC actions resulting from its last public meeting on November 13 and 14, 2007.

DATES: The teleconference call will take place on Wednesday, February 27, 2008, from 1:30 p.m. until approximately 3 p.m. Eastern Standard Time.

ADDRESSES: Committee members and members of the public may participate by dialing 1–877–451–9782 on a touch-tone phone. You will then be prompted to enter your ''participant code number,'' which is 9559674#. Please ensure that you enter the # mark after the participant code. Public participation is welcomed; however, the number of teleconference lines is limited, and lines are available first-come, first-served. Members of the public may also participate by coming to Room 1116 U.S. Coast Guard Headquarters; 2100 Second Street, SW., Washington, DC 20593–0001. We request that members of the public who plan to attend this meeting notify Mr. Mike Rosecrans at 202–372–1245 so that

he may notify building security officials. You may also gain access to this docket at *http://dms.dot.gov/search/searchFormSimple.cfm*. Background information is available at *http://www.fishsafe.info*.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Rosecrans, Assistant Executive Director of CFIVSAC, telephone 202–372–1245, fax 202–372–1917.

SUPPLEMENTARY INFORMATION: The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register** [5 U.S.C. App. (Pub. L. 92–463)]. CFIVSAC is chartered under that Act. It provides advice and makes recommendations to the Secretary on issues regarding safety of commercial fishing industry vessels.

Tentative Agenda: Wednesday, February 27, 2008 1:30 p.m.: Welcome, introduction of new members and Opening Remarks—CFIVSAC Chairman Mr. Jerry Dzugan.

Open discussion concerning the work of the Communications Subcommittee and Task 07–01 Completion of Fishing Vessel Digest.

Discussion of the work of the Risk Management Subcommittee and Task 07–02—Roles and Mission and Risk Management Best Practices.

Discussion of Task 07–03—Long Range Goals for the Committee.

Public comment period.

Discussion of plans for next meeting.

3 p.m.: Adjourn.

This tentative agenda is subject to change and the meeting may adjourn early if all

Committee business has been completed.

Public Participation

The Chairman of CFIVSAC is empowered to conduct the teleconference in a way that will, in his judgment, facilitate the orderly conduct of business. During its teleconference, the Committee welcomes public comment. The Committee will make every effort to hear the views of all interested parties, including the public. Written comments may be submitted to Mr. Mike Rosecrans, Assistant Executive Director, CFIVSAC; Commandant (CG–5433); 2100 Second Street, SW., Washington, DC 20593–0001.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Mr. Rosecrans as soon as possible.

Dated: February 7, 2008.

H.L. Hime,

Acting Director of Commercial Standards and Regulations.

[FR Doc. 08–656 Filed 2–8–08; 1:54 pm]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of SGS North America, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, SGS North America, Inc., 2 Avenue J, Bayonne, NJ 07002, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.*

DATES: The accreditation and approval of SGS North America, Inc., as commercial gauger and laboratory became effective on September 20, 2007. The next triennial inspection date will be scheduled for September 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 08–589 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–M

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Inspectorate America Corporation, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Inspectorate America Corporation, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Inspectorate America Corporation, 1404 Joliet Road, Suite G, Romeoville, IL 60446, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*.

DATES: The accreditation and approval of Inspectorate America Corporation, as commercial gauger and laboratory became effective on August 08, 2007. The next triennial inspection date will be scheduled for August 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2431 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Inspectorate America Corporation, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Inspectorate America Corporation, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Inspectorate America Corporation, 37 Panagrossi Circle, East Haven, CT 06512, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*.

DATES: The accreditation and approval of Inspectorate America Corporation, as commercial gauger and laboratory became effective on July 25, 2007. The next triennial inspection date will be scheduled for July 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2433 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Intertek USA, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Intertek USA, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Intertek USA, Inc., 725 Oakridge Dr., Romeoville, IL 60446, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*.

DATES: The accreditation and approval of Intertek USA, Inc., as commercial gauger and laboratory became effective on August 10, 2007. The next triennial inspection date will be scheduled for August 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2434 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of SGS North America, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, SGS North America, Inc., 99 Castle Coakley, Christiansted, St. Croix, VI 00820, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*.

DATES: The accreditation and approval of SGS North America, Inc., as commercial gauger and laboratory became effective on July 19, 2007. The next triennial inspection date will be scheduled for July 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2430 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2405 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2435 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Camin Cargo Control, Inc., 230 Marion Ave., Linden, NJ 07036, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*.

DATES: The accreditation and approval of Camin Cargo Control, Inc., as commercial gauger and laboratory became effective on May 03, 2007. The next triennial inspection date will be scheduled for May 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Camin Cargo Control, Inc., 1550 Industrial Park Drive, Nederland, TX 77627, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation and approval of Camin Cargo Control, Inc., as commercial gauger and laboratory became effective on March 12, 2007. The next triennial inspection date will be scheduled for March 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Chem Coast, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Chem Coast, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Chem Coast, Inc., 11820 North H Street, Laporte, TX 77571, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*.

DATES: The accreditation and approval of Chem Coast, Inc., as commercial gauger and laboratory became effective on March 19, 2007. The next triennial inspection date will be scheduled for March 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2404 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Inspectorate America Corporation as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Inspectorate America Corporation as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Inspectorate America Corporation, 1150–80 Sylvan Street, Linden, NJ 07036, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*.

DATES: The accreditation and approval of Inspectorate America Corporation as commercial gauger and laboratory became effective on March 28, 2007. The next triennial inspection date will be scheduled for March 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2402 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Inspectorate America Corporation, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Inspectorate America Corporation, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Inspectorate America Corporation, 6175 Hwy 347, Beaumont, TX 77705, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The accreditation and approval of Inspectorate America Corporation, as commercial gauger and laboratory became effective on May 16, 2007. The next triennial inspection date will be scheduled for May 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2437 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Intertek USA, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Intertek USA, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Intertek USA, Inc., 16640 B Jacintoport Blvd., Houston (Channelview), TX 77015, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*.

DATES: The accreditation and approval of Intertek USA, Inc., as commercial gauger and laboratory became effective on May 21, 2007. The next triennial inspection date will be scheduled for May 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2400 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of NMC Global Corporation, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of NMC Global Corporation as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, NMC Global Corporation, 326 23rd St., Kenner, LA 70062, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.*

DATES: The accreditation and approval of NMC Global Corporation as a commercial gauger and laboratory became effective on May 1, 2007. The next triennial inspection date will be scheduled for May 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, (202) 344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2401 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 19 CFR 151.13, Saybolt LP, 4871 Sunrise Dr., suite 102, Martinez, CA 94553, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.*

DATES: The accreditation and approval of Saybolt LP, as commercial gauger and laboratory became effective on March 6, 2007. The next triennial inspection date will be scheduled for March 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2406 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

Approval of Inspectorate America Corporation, as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of Inspectorate America Corporation, as a commercial gauger.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.13, Inspectorate America Corporation, 3306 Loop 197 North, Texas City, TX 77590, has been approved to gauge petroleum, petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.13. Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/.*

DATES: The approval of Inspectorate America Corporation, as commercial gauger became effective on March 15, 2007. The next triennial inspection date will be scheduled for March 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2403 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Approval of SGS North America, Inc., as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of approval of SGS North America, Inc., as a commercial gauger.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.13, SGS North America, Inc., 2301 Brazosport Blvd., Suite A 915, Freeport, TX 77541, has been approved to gauge petroleum, petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.13. Anyone wishing to employ this entity to conduct gauger services should request and receive written assurances from the entity that it is approved by the U.S. Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger service this entity is approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/commercial_gaugers/*

DATES: The approval of SGS North America, Inc., as commercial gauger became effective on May 18, 2007. The next triennial inspection date will be scheduled for May 2010.

FOR FURTHER INFORMATION CONTACT: Commercial Gauger Laboratory Program Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: January 31, 2008.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E8–2436 Filed 2–11–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R2–ES–2008–N003; 20124–1113–0000–F5]

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications.

SUMMARY: The following applicants have applied for scientific research permits to conduct certain activities with endangered species pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended.

DATES: To ensure consideration, written comments must be received on or before March 13, 2008.

ADDRESSES: Written comments should be submitted to the Chief, Endangered Species Division, Ecological Services, P.O. Box 1306, Room 4102, Albuquerque, New Mexico 87103. Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act. Documents will be available for public inspection, by appointment only, during normal business hours at the U.S. Fish and Wildlife Service, 500 Gold Ave. SW., Room 4102, Albuquerque, New Mexico. Please refer to the respective permit number for each application when submitting comments.

FOR FURTHER INFORMATION CONTACT: Chief, Endangered Species Division, P.O. Box 1306, Room 4102, Albuquerque, New Mexico 87103, (505) 248–6920.

SUPPLEMENTARY INFORMATION:

Public Availability Of Comments

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Permit TE–797127

Applicant: U.S. Army Corps of Engineers, Albuquerque, New Mexico.

Applicant requests an amendment to an existing permit for research and recovery purposes to conduct presence/absence and collections of the following endangered plant species: Holy Ghost ipomopsis (*Ipomopsis sancti-spiritus*), Knowlton cactus (*Pediocactus knowltonii*), Kuenzler's hedgehog cactus (*Echinocereus fendleri* var. *kuenzleri*), Mancos milk-vetch (*Astragalus humillimus*), Sacramento prickly poppy (*Argemone pleiacantha* spp. *pinnatisecta*), Sneed pincushion cactus (*Coryphantha sneedii* var. *sneedii*), Todsen's pennyroyal (*Hedeoma todsenii*), Gypsum wild-buckwheat (*Eriogonum gypsophilum*), Lee pincushion cactus (*Coryphantha sneedii* var. *leei*), Mesa Verde cactus (*Sclerocactus mesae-verdae*), Pecos sunflower (*Helianthus paradoxus*), Sacramento Mountains thistle (*Cirsium vinaceum*), and Zuni fleabane (*Erigeron rhizomatus*) within New Mexico.

Permit TE–172278

Applicant: John Abbott, Austin, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys of the American burying beetle (*Nicrophorus americanus*) within Texas.

Permit TE–172461

Applicant: Raymond Matlack, Canyon, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys of the lesser long-nosed bat (*Leptonycteris curasoae yerbabuenae*) within Arizona.

Permit TE–028362

Applicant: Bureau of Land Management—Arizona Strip, St. George, Utah.

Applicant requests an amendment to a previous permit for research and recovery purposes to conduct recovery activities for the desert tortoise (*Gopherus agassizii*) within Mohave and Coconino counties, Arizona.

Permit TE–069184

Applicant: Turner Endangered Species Fund, Bozeman, Montana.

Applicant requests an amendment to a previous permit to conduct presence/absence surveys for research and recovery purposes for northern aplomado falcon (*Falco fermoralis septentrionalis*) within New Mexico.

Authority: 16 U.S.C. 1531, *et seq.*

Dated: January 17, 2008.

Christopher T. Jones,

Acting Regional Director, Southwest Region, Fish and Wildlife Service.

[FR Doc. E8–2549 Filed 2–11–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of Final Comprehensive Conservation Plan for Rainwater Basin Wetland Management District, Kearney, NE

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: The U.S. Fish and Wildlife Service (Service) announces that the final Comprehensive Conservation Plan (CCP) for the Rainwater Basin Wetland Management District (WMD) is available. This CCP, prepared pursuant to the National Wildlife Refuge System Improvement Act of 1997 and the National Environmental Policy Act of 1969, describes how the Service intends to manage the Rainwater Basin WMD, which administers 61 waterfowl production areas and 35 conservation easements for the next 15 years.

ADDRESSES: A copy of the CCP or Summary may be obtained by writing to U.S. Fish and Wildlife Service, Division of Refuge Planning, 134 Union Boulevard, Suite 300, Lakewood, Colorado 80228; or download from *http://mountain-prairie.fws.gov/planning.*

FOR FURTHER INFORMATION CONTACT: Bernardo Garza, 303–236–4377 (phone); 303–236–4792 (fax); or *bernardo_garza@fws.gov*.

SUPPLEMENTARY INFORMATION:

Background

The District encompasses Adams, Clay, Fillmore, Franklin, Gosper, Hall, Hamilton, Kearney, Phelps, Polk, Saline, Seward, and York Counties in south-central Nebraska.

The WMD was established in 1963 when the Service began acquiring critical migratory waterfowl habitat in south-central and southeast Nebraska with Duck Stamp dollars. The WMD's establishment purposes are:

(1) ''* * * to assure the long-term viability of the breeding waterfowl population and production through the acquisition and management of Waterfowl Production Areas (WPAs), while considering the needs of other migratory birds, threatened and endangered species and other wildlife.'' (purpose statement developed for all WMDs in Region 6 in June 2004);

(2) To acquire small wetland and pothole areas to be designated as 'Waterfowl Production Areas' as an inviolate sanctuary or for any other management purpose, for migratory birds and to restore and develop adequate wildlife habitat under the Migratory Bird Hunting and Conservation Stamp Promotion Act ''see'' [16 U.S.C. 715d(2), 715i(a) & 718(c)];

(3) ''for conservation purposes'' under the Consolidated Farm and Rural Development Act [7 U.S.C. 2002 (a)];

(4) ''promote * * * the conservation of the wetlands of the Nation in order to maintain the public benefits they provide and to help fulfill international obligations in various migratory bird treaties and conventions with Canada, Mexico, Japan, the Union of Soviet Socialist Republics, and with various countries in the Western Hemisphere'' under the Emergency Wetlands Resources Act [16 U.S.C. 3901(b)]; and

(5) ''to protect waterfowl production areas'' under Public Land Orders 6979 [May 25, 1993], and 7206 [June 24, 1996].

Today, the WMD manages 24,210.09 acres in 61 waterfowl production areas within the geographic area called the Rainwater Basin. Current public use opportunities at this WMD include hunting, environmental education and interpretation, wildlife observation, and photography. All WPAs are subject to all provisions of the Migratory Bird Conservation Act except the inviolate sanctuary provisions, for any other management purposes, for migratory birds, and for conservation purposes.

This final CCP identifies goals, objectives, and strategies for the management of Rainwater Basin WMD that emphasize restoration and maintenance of native habitats in vigorous condition for migratory birds. The CCP places high importance on the control of invasive plant species with partners and integrated pest management. It seeks to provide habitats in order to contribute to conservation, enhancement, and production of migratory bird species while protecting federally listed species.

The availability of the draft CCP and Environmental Assessment (EA) for a 30-day public review and comment period was announced in the **Federal Register** on July 18, 2007. The draft CCP/EA evaluated two alternatives for managing Rainwater Basin WMD for the next 15 years.

The preferred alternative will expand the scope and level of efforts of the current management of habitats by maintaining existing and seeking new partnerships. This alternative will seek to address all management aspects in a holistic manner. The WMD will work with formal and informal partnerships, including landowners, to improve waterfowl production areas at a landscape level. Actions would strive to build a ''neighborly interaction'' between privately-owned, State, and WMD lands within each watershed. The WMD would work with partners to complete the engineering and funding and would continue to support and work cooperatively to further the goals of the Rainwater Basin Joint Venture.

This alternative was selected because it best meets the purposes and goals of the WMD, as well as the mission and goals of the National Wildlife Refuge System. The preferred alternative also will benefit federally listed species, shore birds, migrating and nesting waterfowl, neotropical migrants, and resident wildlife. Environmental education and partnerships will result in improved wildlife-dependent recreational opportunities. Cultural and historical resources as well as federally listed species will be protected.

The Service is furnishing this notice to advise other agencies and the public of the availability of the final Plan, to provide information on the desired conditions for the Wetland Management District, and to detail how the Service will implement management strategies. Based on the review and evaluation of the information contained in the EA, the Regional Director has determined that implementation of the Final Plan does not constitute a major federal action that would significantly affect the quality of the human environment within the meaning of Section 102(2) (c) of the National Environmental Policy Act. Therefore, an Environmental Impact Statement will not be prepared.

Dated: February 5, 2008.

Gary G. Mowad,

Acting Regional Director, Denver, Colorado.

[FR Doc. E8–2541 Filed 2–11–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Certificate of Degree of Indian or Alaska Native Blood Information Collection (CDIB), Submission

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of submission of information collection.

SUMMARY: The Bureau of Indian Affairs (BIA) is submitting to OMB an information collection from persons seeking proof of American Indian or Alaska Native blood for reinstatement, as required by the Paperwork Reduction Act. The information collected under OMB Control No. 1076–0153 will be used to document an applicant's Indian

ancestry and degree of Indian or Alaska Native blood. CDIBs are used by individuals applying for BIA programs and services available to Indians because they are Indian.

DATES: Submit comments on or before March 13, 2008.

ADDRESSES: Submit comments on the information collection to the Desk Officer for the Department of the Interior either by facsimile at 202–395–6566 or by e-mail at *OIRA_DOCKET@omb.eop.gov*. Please submit copy of comments to Iris Drew, Office of Indian Services, Bureau of Indian Affairs, 1001 Indian School Road, NW., Albuquerque, New Mexico 87104. Fax number: (505) 563–3060.

FOR FURTHER INFORMATION CONTACT: Ms. Iris Drew, Tribal Relations Specialist, Tribal Government Services, (505) 563–3530.

SUPPLEMENTARY INFORMATION: This collection was originally approved and assigned OMB Control No. 1076–0153 when it was submitted with a proposed rulemaking, 25 CFR part 70, which was published in the **Federal Register** on April 18, 2000 (66 FR 20775). The proposed rulemaking was not finalized due to various reasons. We are in the process of revising the proposed rulemaking for processing applications for Certificates of Degree of Indian or Alaska Native Blood (CDIB). A request for comments on this information collection request appeared in the **Federal Register** (72 FR 61366) on October 30, 2007. One comment was received during or before the close of the public comment period of December 31, 2007.

Comment: We received one comment regarding (1) who needs to fill out the form? Is it to be used only for new recognition applications or for all enrolled persons; (2) does this establish a new ''blood'' requirement, i.e., ⅛ or ¼?; and (3) do not reinvent Enrollment for those who have already done it but have reasonable requirements for new enrollees or those denied.

Response: (1) Most of the individuals who fill out the form are non-enrolled Indians who wish to document their Indian or Alaska native ancestry. Non-enrolled persons with one-quarter (¼) or more degree Indian blood may be eligible to receive various services provided to Indians and Alaska Natives by the Bureau of Indian Affairs. Other Federal Agencies will accept a CDIB as proof of Indian ancestry. In general, enrolled tribal members who can show proof of tribal membership do not need a CDIB to demonstrate eligibility for services.

(2) Minimum Indian blood degree requirements are established by Congress through federal statute or by tribes and Alaska Native villages through tribal law. The Certificate Degree of Indian or Alaska Native Blood does not establish a new ''blood'' requirement. Rather, CDIBs are used by individuals who want to document their Indian or Alaska native ancestry and degree of Indian blood. CDIBs do not establish membership in any Indian or Alaska Native tribe.

(3) A CDIB is not an enrollment document. Tribes determine their own membership and the BIA does not enroll tribal members.

Request for Comments: The Bureau of Indian Affairs requested comments about the proposed collection to evaluate:

(a) The accuracy of the burden hours, including validity of the methodology used and assumptions made;

(b) The necessity of the information for proper performance of the bureau functions, including its practical utility;

(c) The quality, utility and clarity of the information to be collected; and

(d) Suggestions to reduce the burden including use of automated, electronic, mechanical, or other forms of information technology.

The public is advised that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information that does not display a valid OMB clearance number. For example, this collection is listed by OMB as control No. 1076–0153, and it expired 11/30/07. The response is voluntary to obtain or retain a benefit.

Please submit your comments to the persons listed in the **ADDRESSES** section. Please note that comments, names and addresses of commentators, are open for public review. Be aware that your name and address may be available to the public on the OMB Web site. We cannot guarantee that your personal information will be safeguarded.

Your comments should address: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents, such as through the use of automated collection techniques or other forms of information technology.

OMB has up to 60 days to make a decision on the submission for renewal, but may make the decision after 30 days. Therefore, to receive the best consideration of your comments, you should submit them closer to 30 days than 60 days.

OMB Approval Number: 1076–0153.

Title: Request for Certificate of Degree of Indian or Alaska Native Blood, 25 CFR part 70.

Brief Description of Collection: Submission of this information is voluntary. However, not providing information may result in a determination that an individual is not eligible to receive program services based upon his/her status as an American Indian or Alaska Native. The information to be collected includes: Certificates of birth and death, probate determinations, court orders, affidavits, Federal or Tribal census records and Social Security records.

Type of Review: Reinstatement.

Respondents: Individual Indians who may be eligible to receive program services based upon their status and/or degree of Indian or Alaska Native blood.

Number of Respondents: 154,980.

Estimated Time per Response: The reporting and record keeping burden for this collection of information is estimated to average 1.5 hours for each response for an estimate 154,980 requests per year or 232,470 hours, including the time for reviewing instructions, searching existing data sources and gathering needed data. Thus, the estimated total annual reporting and record keeping burden for this entire collection is estimated to be 232,470 hours.

Frequency of Response: All information and documentation is to be collected once from each requester.

Total Annual Burden to Respondents: 232,470 hours.

Total Annual Cost to Respondents: $6,199,200.

Dated: February 6, 2008.

Carl J. Artman,

Assistant Secretary—Indian Affairs.

[FR Doc. E8–2535 Filed 2–11–08; 8:45 am]

BILLING CODE 4310–4J–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Notice of Deadline for Submitting Completed Applications To Begin Participation in the Tribal Self-Governance Program in Fiscal Year 2009 or Calendar Year 2009

AGENCY: Office of Self-Governance, Bureau of Indian Affairs, Interior.

ACTION: Notice of Application Deadline.

SUMMARY: In this notice, the Office of Self-Governance (OSG) establishes a March 3, 2008, deadline for tribes/consortia to submit completed applications to begin participation in the tribal self-governance program in fiscal year 2009 or calendar year 2009.

DATES: Completed application packages must be received by the Director, Office of Self-Governance, by March 3, 2008.

ADDRESSES: Application packages for inclusion in the applicant pool should be sent to Ms. Sharee M. Freeman, Director, Office of Self-Governance, Department of the Interior, Mail Stop 355–G–SIB, 1951 Constitution Avenue, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Dr. Kenneth D. Reinfeld, Office of Self-Governance, Telephone 202–208–5734.

SUPPLEMENTARY INFORMATION: Under the Tribal Self-Governance Act of 1994 (Pub. L. 103–413), as amended by the Fiscal Year 1997 Omnibus Appropriations Bill (Pub. L. 104–208), the Director, Office of Self-Governance may select up to 50 additional participating tribes/consortia per year for the tribal self-governance program, and negotiate and enter into a written funding agreement with each participating tribe. The Act mandates that the Secretary submit copies of the funding agreements at least 90 days before the proposed effective date to the appropriate committees of the Congress and to each tribe that is served by the Bureau of Indian Affairs (BIA) agency that is serving the tribe that is a party to the funding agreement. Initial negotiations with a tribe/consortium located in a region and/or agency which has not previously been involved with self-governance negotiations, will take approximately 2 months from start to finish. Agreements for an October 1 to September 30 funding year need to be signed and submitted by July 1. Agreements for a January 1 to December 31 funding year need to be signed and submitted by October 1.

Purpose of Notice

25 CFR Parts 1000.10 to 1000.31 will be used to govern the application and selection process for tribes/consortia to begin their participation in the tribal self-governance program in fiscal year 2009 and calendar year 2009. Applicants should be guided by the requirements in these subparts in preparing their applications. Copies of these subparts may be obtained from the information contact person identified in this notice.

Tribes/consortia wishing to be considered for participation in the tribal self-governance program in fiscal year 2009 or calendar year 2009 must respond to this notice, except for those which are: (1) Currently involved in negotiations with the Department; (2) one of the 95 tribal entities with signed agreements; or (3) one of the tribal entities already included in the applicant pool as of the date of this notice.

Dated: January 16, 2008.

Carl J. Artman,

Assistant Secretary—Indian Affairs.

[FR Doc. E8–2574 Filed 2–11–08; 8:45 am]

BILLING CODE 4310–W8–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Pit River Tribe Liquor Control Ordinance

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the Pit River Tribe Liquor Control Ordinance. The Ordinance regulates and controls the possession, sale and consumption of liquor within the Pit River tribal land. The tribal land is located on trust land and this Ordinance allows for the possession and sale of alcoholic beverages. This Ordinance will increase the ability of the tribal government to control the distribution and possession of liquor within their tribal land, and at the same time will provide an important source of revenue and strengthening of the tribal government and the delivery of tribal services.

DATES: Effective Date: This Ordinance is effective February 12, 2008.

FOR FURTHER INFORMATION CONTACT: Fred Doka Jr., Tribal Operations Officer, Pacific Regional Office, 2800 Cottage Way, Sacramento, CA 95825, Telephone (916) 978–6067; or Elizabeth Colliflower, Office of Tribal Services, 1849 C Street, NW., Mail Stop 4513–MIB, Washington, DC 20240; Telephone (202) 513–7627; Fax (202) 501–0679.

SUPPLEMENTARY INFORMATION: Pursuant to the Act of August 15, 1953, Public Law 83–277, 67 Stat. 586, 18 U.S.C. 1161, as interpreted by the Supreme Court in *Rice* v. *Rehner*, 463 U.S. 713 (1983), the Secretary of the Interior shall certify and publish in the **Federal Register** notice of adopted liquor ordinances for the purpose of regulating liquor transactions in Indian country. The Pit River Tribal Council adopted this Liquor Control Ordinance on September 7, 2007. The purpose of this Ordinance is to govern the sale, possession and distribution of alcohol within the Pit River tribal lands.

This notice is published in accordance with the authority delegated by the Secretary of the Interior to the Assistant Secretary-Indian Affairs. I certify that this Liquor Control Ordinance of the Pit River Tribe was duly adopted by the Tribal Council on September 7, 2007.

Dated: February 6, 2008.

Carl J. Artman,

Assistant Secretary—Indian Affairs.

The Pit River Tribe Liquor Control Ordinance reads as follows:

Pit River Liquor Control Ordinance

07–03–38

Chapter I—Introduction

Section 101. Title. This ordinance shall be known as the Pit River Liquor Control Ordinance.

Section 102. Authority. This ordinance is enacted pursuant to the Act of August 15, 1953, 67 Stat. 586, codified at 18 U.S.C. 1161, and by the authority of the Pit River Tribal Council.

Section 103. Purpose. The purpose of this ordinance is to regulate and control the possession and sale of liquor on all lands within the jurisdiction of the Pit River Tribe. The enactment of a tribal ordinance governing liquor possession and sale on lands located within the Tribe's jurisdiction will increase the ability of the tribal government to control the sale, distribution and possession of liquor on such lands and will provide an important source of revenue for the continued operation and strengthening of the tribal government and the delivery of tribal government services.

Section 104. Effective Date. This ordinance shall be effective on certification by the Secretary of the Interior and its publication in the **Federal Register**.

Article 1. Declaration of public policy and purpose.

(a) The introduction, possession, and sale of liquor on lands located within the Tribe's jurisdiction is a matter of special concern to the Tribe.

(b) Federal law currently prohibits the introduction of liquor into Indian Country (18 U.S.C. 1154), except as provided therein and expressly delegates to tribes the decision regarding when and to what extent liquor transactions shall be permitted. (18 U.S.C. 1161).

(c) The Council recognizes that a need exists for strict regulation and control

over liquor transactions on lands within the Tribe's jurisdiction, because of the many potential problems associated with the unregulated or inadequately regulated sale, possession, distribution, and consumption of liquor. The Council finds that tribal control and regulation of liquor is necessary to achieve maximum economic benefit to the Tribe, to protect the health and welfare of tribal members, and to address specific concerns relating to alcohol use on lands within the Tribe's jurisdiction.

(d) It is in the best interests of the Tribe to enact a tribal ordinance governing liquor sales on lands within the Tribe's jurisdiction which provides for exclusive purchase, distribution, and sale of liquor only on such lands. Further, the Tribe has determined that said purchase, distribution, and sale shall take place only at tribally-owned enterprises and/or tribally licensed establishments operating on lands within the Tribe's jurisdiction.

Article II. Definitions.

As used in this title, the following words shall have the following meanings unless the context clearly requires otherwise:

(a) ''*Alcohol*'' means that substance known as ethyl alcohol, hydrated oxide of ethyl, ethanol, or spirits of wine, from whatever source or by whatever process produced.

(b) ''*Alcoholic Beverage*'' is synonymous with the term ''liquor'' as defined in Article II(e) of this Chapter.

(c) ''*Bar*'' means any establishment with special space and accommodations for the sale of liquor by the glass and for consumption on the premises as herein defined.

(d) ''*Beer*'' means any beverage obtained by the alcoholic fermentation of an infusion or decoction of pure hops, or pure extract of hops and pure barley malt or other wholesome grain or cereal in pure water and containing the percent of alcohol by volume subject to regulation as an intoxicating beverage in the state where the beverage is located.

(e) ''*Liquor*'' includes all fermented, spirituous, vinous, or malt liquor or combinations thereof, and mixed liquor, a part of which is fermented, and every liquid or solid or semisolid or other substance, patented or not, containing distilled or rectified spirits, potable alcohol, beer, wine, brandy, whiskey, rum, gin, aromatic bitters, and all drinks or drinkable liquids and all preparations or mixtures capable of human consumption and any liquid, semisolid, solid, or other substances, which contains more than one half of one percent of alcohol.

(f) ''*Liquor Store*'' means any store at which liquor is sold and, for the purpose of this ordinance, including stores only a portion of which are devoted to the sale of liquor or beer.

(g) ''*Malt Liquor*'' means beer, strong beer, ale, stout and porter.

(h) ''*Package*'' means any container or receptacle used for holding liquor.

(i) ''*Public Place*'' includes state or county or tribal or federal highways or roads; buildings and grounds used for school purposes; public dance halls and grounds adjacent thereto; soft drink establishments, public buildings, public meeting halls, lobbies, halls and dining rooms of hotels, restaurants, theaters, gaming facilities, entertainment centers, stores, garages, and filling stations which are open to and/or are generally used by the public and to which the public is permitted to have unrestricted access; public conveyances of all kinds and character; and all other places of like or similar nature to which the general public has unrestricted right of access, and which are generally used by the public. For the purpose of this ordinance, ''Public Place'' shall also include any establishment other than a single family home which is designed for or may be used by more than just the owner of the establishment.

(j) ''*Sale*'' and ''*Sell*'' include exchange, barter and traffic; and also include the selling or supplying or distributing, by any means whatsoever, of liquor, or of any liquid known or described as beer or by any name whatsoever commonly used to describe malt or brewed liquor or of wine by any person to any person.

(k) ''*Spirits*'' means any beverage which contains alcohol obtained by distillation, including wines exceeding seventeen percent of alcohol by weight.

(l) ''*Tribal Council*'' means the Pit River Tribal Council.

(m) ''*Wine*'' means any alcoholic beverage obtained by fermentation of the natural contents of fruits, vegetables, honey, milk, or other products containing sugar, whether or not other ingredients are added, to which any saccharine substances may have been added before, during or after fermentation, and containing not more than seventeen percent of alcohol by weight, including sweet wines fortified with wine spirits, such as port, sherry, muscatel and angelica, not exceeding seventeen percent of alcohol by weight.

Article III. Powers of Enforcement.

Section 1. The Tribal Council. In furtherance of this ordinance, the Tribal Council shall have the following powers and duties:

(a) To publish and enforce rules and regulations adopted by the Tribal Council governing the sale, manufacture, distribution, and possession of alcoholic beverages on lands within the Tribe's jurisdiction;

(b) To employ managers, accountants, security personnel, inspectors and such other persons as shall be reasonably necessary to allow the Tribal Council to perform its functions. Such employees shall be tribal employees;

(c) To authorize a representative in respect to the enforcement of this ordinance to issue licenses permitting the sale or manufacture or distribution of liquor on lands within the Tribe's jurisdiction and to revoke such licenses as provided herein;

(d) To hold hearings on violations of this ordinance or for the issuance or revocation of licenses hereunder;

(e) To bring suit in the appropriate court to enforce this ordinance as necessary;

(f) To authorize a representative in respect to the enforcement of this ordinance to collect taxes and fees levied or set by the Tribal Council and to keep accurate records, books, and accounts;

(h) To determine and seek damages for violation of the ordinance.

Section 2. Limitations on Powers. In the exercise of its powers and duties under this ordinance, the Tribal Council and its individual members shall not:

(a) Accept any gratuity, compensation or other thing of value from any liquor wholesaler, retailer, or distributor or from any licensee;

(b) Waive the immunity of the Tribe from suit without the express consent of the members of the Pit River Tribe.

Section 3. Inspection Rights. The premises on which liquor is sold or distributed shall be open for inspection by the Tribal Council and/or its representative in respect to the enforcement of this ordinance at all reasonable times for the purpose of ascertaining whether the rules and regulations of the Tribal Council and this ordinance are being complied with.

Article IV. Sales of Liquor.

Section 1. License Required. Sales of liquor and alcoholic beverages on lands within the Tribe's jurisdiction may only be made at businesses which hold a Tribal Liquor License.

Section 2. Sales for Cash. All liquor sales on lands within the Tribe's jurisdiction shall be on a cash only basis and no credit shall be extended to any person, organization, or entity, except that this provision does not prevent the payment for purchases with the use of credit or debit cards such as Visa, MasterCard, American Express, etc.

Section 3. Sale for Personal Consumption. All sales shall be for the personal use and consumption of the purchaser. Resale of any alcoholic

beverage purchased on lands within the Tribe's jurisdiction is prohibited. Any person who is not licensed pursuant to this ordinance who purchases an alcoholic beverage on lands within the Tribe's jurisdiction and sells it, whether in the original container or not, shall be guilty of a violation of this ordinance and shall be subject to paying damages to the Tribe as set forth herein.

Article V. Licensing.

Section 1. Procedure. In order to control the proliferation of establishments on lands within the Tribe's jurisdiction which sell or serve liquor by the bottle or by the drink, all persons or entities which desire to sell liquor on lands within the Tribe's jurisdiction must apply to the Tribe for a license to sell or serve liquor.

Section 2. Application. Any person or entity applying for a license to sell or serve liquor on lands within the Tribe's jurisdiction must fill in the application provided for this purpose by the Tribe and pay such application fee as may be set from time to time by the Tribal Council for this purpose. Said application must be filled out completely in order to be considered.

Section 3. Issuance of License. The Tribal Council or, if so authorized, a representative in respect to the enforcement of this ordinance, may issue a license if it believes that such issuance is in the best interests of the Tribe and its members.

Section 4. Period of License. Each license may be issued for a period not to exceed two (2) years from the date of issuance.

Section 5. Renewal of License. A licensee may renew its license if the licensee has complied in full with this ordinance provided however, that the Tribal Council's representative in respect to the enforcement of this ordinance, or in the absence thereof the Tribal Council may refuse to renew a license if it finds that doing so would not be in the best interests of the health and safety of the Tribe.

Section 6. Revocation of License. The Tribal Council's representative in respect to the enforcement of this ordinance or, in the absence thereof, the Tribal Council may revoke a license for reasonable cause upon notice and hearing at which the licensee is given an opportunity to respond to any charges against it and to demonstrate why the license should not be suspended or revoked.

Section 7. Transferability of License. Licenses issued by the Tribal Council's representative in respect to the enforcement of this ordinance or, in the absence thereof, the Tribal Council shall not be transferable and may only be utilized by the person or entity in whose name it was issued.

Article VI. Taxes.

Section 1. Sales Tax. There is hereby levied and shall be collected a tax on each retail sale of liquor or alcoholic beverage on lands within the Tribe's jurisdiction in the amount of one percent (1%) of the retail sales price. All taxes from the sale of liquor and alcoholic beverages on lands within the Tribe's jurisdiction shall be paid over to the General Fund of the Tribe.

Section 2. Taxes Due. All taxes for the sale of liquor and alcoholic beverages on lands within the Tribe's jurisdiction are due on the 15th day of the month following the end of the calendar quarter for which the taxes are due.

Section 3. Delinquent Taxes. Past due taxes shall accrue interest at 2% per month.

Section 4. Reports. Along with payment of the taxes imposed herein, the taxpayer shall submit a quarterly accounting of all income from the sale or distribution of liquor, as well as for the taxes collected.

Section 5. Audit. As a condition of obtaining a license, the licensee must agree to the review or audit of its books and records relating to the sale of liquor and alcoholic beverages on lands within the Tribe's jurisdiction. Said review or audit may be done periodically by the Tribe through its agents or employees whenever, in the opinion of the Tribal Council or its representative for purposes of enforcing this ordinance, such a review or audit is necessary to verify the accuracy of reports.

Article VII. Rules, Regulations, and Enforcement.

Section 1. In any proceeding under this ordinance, conviction of one unlawful sale or distribution of liquor shall establish prima facie intent of unlawfully keeping liquor for sale, selling liquor or distributing liquor in violation of this ordinance.

Section 2. Any person who shall sell or offer for sale or distribute or transport in any manner liquor in violation of this ordinance, or who shall operate or shall have liquor for sale in his possession without a license, shall be guilty of a violation of this ordinance, subjecting him or her to civil damages assessed by the Tribal Council.

Section 3. Any person within the boundaries of lands within the Tribe's jurisdiction who buys liquor from any person other than a properly licensed facility shall be guilty of a violation of this ordinance.

Section 4. Any person who keeps or possesses liquor upon his person or in any place or on premises conducted or maintained by his principal or agent with the intent to sell or distribute it contrary to the provisions of this title, shall be guilty of a violation of this ordinance.

Section 5. Any person who knowingly sells liquor to a person who appears to be intoxicated shall be guilty of a violation of this ordinance.

Section 6. Any person engaging wholly or in part in the business of carrying passengers for hire, and every agent, servant, or employee of such person, who shall knowingly permit any person to drink liquor in any public conveyance shall be guilty of an offense. Any person who shall drink liquor in a public conveyance shall be guilty of a violation of this ordinance.

Section 7. No person under the age of 21 years shall consume, acquire or have in his possession any liquor or alcoholic beverage. No person shall permit any other person under the age of 21 to consume liquor on his premises or any premises under his control except in those situations set out in this section. Any person violating this section shall be guilty of a separate violation of this ordinance for each and every drink so consumed.

Section 8. Any person who shall sell or provide any liquor to any person under the age of 21 years shall be guilty of a violation of this ordinance for each such sale or drink provided.

Section 9. Any person who transfers in any manner an identification of age to a person under the age of 21 years for the purpose of permitting such person to obtain liquor shall be guilty of an offense; provided, that corroborative testimony of a witness other than the underage person shall be a requirement of finding a violation of this ordinance.

Section 10. Any person who attempts to purchase an alcoholic beverage through the use of false or altered identification which falsely purports to show the individual to be over the age of 21 years shall be guilty of violating this ordinance.

Section 11. Any person guilty of a violation of this ordinance shall be liable to pay the Tribe the amount of $500 per violation as civil damages to defray the Tribe's cost of enforcement of this ordinance.

Section 12. When requested by the provider of liquor, any person shall be required to present official documentation of the bearer's age, signature and photograph. Official documentation includes one of the following:

(1) Tribal identification card;

(2) Driver's license or identification card issued by any state department of motor vehicles;

(3) United States Active Duty Military;

(4) Passport.

Section 13. Liquor which is possessed, including for sale, contrary to the terms of this ordinance is declared to be contraband. Any tribal agent, employee or officer who is authorized by the Tribal Council to enforce this section shall seize all contraband and preserve it in accordance with the provisions established for the preservation of impounded property.

Section 14. Upon being found in violation of the ordinance, the party shall forfeit all right, title and interest in the items seized which shall become the property of the Tribe.

Article VII. Abatement.

Section 1. Any room, house, building, vehicle, structure, or other place where liquor is sold, manufactured, bartered, exchanged, given away, furnished, or otherwise disposed of in violation of the provisions of this ordinance or of any other tribal law relating to the manufacture, importation, transportation, possession, distribution, and sale of liquor, and all property kept in and used in maintaining such place, is hereby declared to be a nuisance.

Section 2. The Chairman of the Tribal Council or, if the Chairman fails or refuses to do so, by a majority vote, the Tribal Council shall institute and maintain an action in the name of the Tribe to abate and perpetually enjoin any nuisance declared under this article. In addition to all other remedies at tribal law, the Court may also order the room, house, building, vehicle, structure, or place closed for a period of one (1) year or until the owner, lessee, tenant, or occupant thereof shall give bond of sufficient sum of not less than $25,000 payable to the Tribe and conditioned that liquor will not be thereafter manufactured, kept, sold, bartered, exchanged, given away, furnished, or otherwise disposed of there in violation of the provisions of this ordinance or of any other applicable tribal law and that he will pay all fines, costs and damages assessed against him for any violation of this ordinance or other tribal liquor laws. If any conditions of the bond be violated, the bond may be recovered for the use of the Tribe.

Section 3. In all cases where any person has been found in violation of this ordinance relating to the manufacture, importation, transportation, possession, distribution, and/or sale of liquor, an action may be brought to abate as a nuisance any real estate or other property involved in the violation of the ordinance and violation of this ordinance shall be *prima facie* evidence that the room, house, building, vehicle, structure, or place against which such action is brought is a public nuisance.

Article IX. Revenue.

Revenue provided for under this ordinance, from whatever source, shall be expended for administrative costs incurred in the enforcement of this ordinance. Excess funds shall be subject to appropriation by the Tribal Council for essential governmental and social services.

Article X. Severability and Effective Date.

Section 1. If any provision or application of this ordinance is determined by review to be invalid, such determination shall not be held to render ineffectual the remaining portions of this ordinance or to render such provisions inapplicable to other persons or circumstances.

Section 2. This ordinance shall be effective on such date as the Secretary of the Interior certifies this ordinance and publishes the same in the **Federal Register**.

Section 3. Any and all prior enactments of the Tribal Council which are inconsistent with the provisions of this ordinance are hereby rescinded.

Article XI. Amendment.

This ordinance may only be amended by a vote of the Tribal Council and subsequent review by the appropriate official of the Department of the Interior and publication in the **Federal Register**.

[FR Doc. E8–2536 Filed 2–11–08; 8:45 am]

BILLING CODE 4310–4J–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–060–5110–GN–CF20; NVN–067930: 8–08807; TAS: 14X5017]

Notice of Intent To Prepare a Supplemental Environmental Impact Statement for the Phoenix Copper Leach Project, Lander County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, 40 CFR 1500–1508, and 43 CFR 3809, the Bureau of Land Management (BLM), Battle Mountain Field Office will prepare a Supplemental Environmental Impact Statement (SEIS) for the Phoenix Copper Leach Project located in Lander County, Nevada. The proposal includes expansion of the existing project boundary, construction and operation of a copper beneficiation facility, and development of new leaching facilities at the Phoenix Mine. This notice initiates the public scoping process and announces a public meeting.

DATES: Written comments on the scope of the SEIS will be accepted until March 13, 2008. A scoping meeting will be held on Wednesday, February 27, 2008 at the Battle Mountain Field Office from 6 p.m. to 8 p.m.

ADDRESSES: Written comments should be mailed to the BLM Battle Mountain Field Office, *ATTN:* Jon Sherve, 50 Bastian Road, Battle Mountain, NV 89820; faxed to *ATTN:* Jon Sherve at (775) 635–4034; or e-mailed to: *phoenix_copper_SEIS@blm.gov*.

FOR FURTHER INFORMATION: Christopher Worthington (775) 635–4144 or e-mail *christopher_worthington@nv.blm.gov*.

SUPPLEMENTARY INFORMATION: Newmont Mining Corporation (Newmont) has submitted an amended Plan of Operations (NVN–067930) to the BLM for the proposed mining project. A third-party contractor will prepare the SEIS under the direction of the BLM pursuant to Council on Environmental Quality regulations 1502.14(a) and 1502.14(d). In addition to the proposed action, the BLM will explore and objectively evaluate all reasonable alternatives, including the alternative of no action.

The proposed project area is located approximately 12 miles southwest of Battle Mountain, Nevada.

Mount Diablo Meridian, Nevada

T. 30 and 31 N., R. 43 E.

The Phoenix Mine is located in the Copper Canyon portion of the Battle Mountain Mining District in Lander County, Nevada. The current project area includes approximately 7,139 acres; 2,865 acres of public land and 4,275 acres privately owned by Newmont. Most of the facilities associated with this proposal will be located on lands previously approved for surface disturbance. This proposed plan would increase the project surface disturbance by approximately 910 acres (185 acres of public land and 725 acres of private land), and includes construction and operation of a new solvent extraction-electrowinning (SX–EW) facility, development of two copper leach facilities, construction of four new process ponds, development of a new clay borrow area, designation of an optional use area that would be used either as a waste rock facility, a tailings facility, copper or gold leach facility, and/or growth media borrow area, and

construction of a new 120-kV power line. Construction and operation of the project is projected to begin in 2008. Active mining for the Phoenix Copper leach project will last about 15 years and will not increase the current life-of-mine for the Phoenix Mine.

An interdisciplinary approach will be used to develop the SEIS, in order to consider the variety of resource issues and concerns identified. Potential significant direct, indirect, residual, and cumulative impacts from the proposed action will be analyzed in the SEIS. Federal, state, and local agencies, as well as individuals or organizations that may be interested in or affected by the BLM's decision on this plan are invited to participate in the scoping process. Federal, state, and local agencies may request or be requested by the BLM to participate as a cooperating agency.

The plan will be presented to the public during a scoping meeting to be held Wednesday, February 27 from 6 p.m. to 8 p.m. at the Battle Mountain Field Office. The plan will be available for public review at Battle Mountain Field Office. The BLM invites public comment on the scope of the analysis, including issues to consider and alternatives to the proposed action. The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis and SEIS alternatives. BLM personnel will be present at the scoping meeting to explain the environmental review process, the mining regulations, and other requirements for processing the proposed plan amendment and the associated SEIS. Representatives of Newmont will be available to describe the proposal.

You may submit comments on issues in writing to the BLM at the public scoping meeting or you may submit them to the BLM using one of the methods listed in the **ADDRESSES** section above. Comments received and a list of attendees at the scoping meeting will be available for public inspection.

Comments and documents pertinent to this proposal, including names and addresses of respondents, may be viewed at the Battle Mountain Field Office during regular business hours (7:30 a.m.–4:30 p.m., Monday through Friday, except holidays).

Comments may be published as part of the SEIS. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so. All submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

(Authority: 43 CFR part 3809)

Dated: January 29, 2008.

Gerald M. Smith,

Field Manager, Battle Mountain Field Office.

[FR Doc. E8–2539 Filed 2–11–08; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

DEPARTMENT OF AGRICULTURE

Forest Service

[UT–070–1320–EL; UTU–84102]

Notice of Intent To Prepare an Environmental Impact Statement and To Conduct Public Scoping on the Greens Hollow Coal Lease Tract

AGENCY: Bureau of Land Management, USDI, and Forest Service, USDA.

ACTION: Notice of Intent to prepare an environmental impact statement (EIS) and to initiate public scoping for the Greens Hollow Coal Lease Tract Lease by Application (LBA) filed by Ark Land Company, a subsidiary of Arch Coal, Inc. in Sanpete and Sevier Counties, Utah.

SUMMARY: Pursuant to Section 102 (2)(C) of the National Environmental Policy Act (NEPA) of 1969, the Bureau of Land Management (BLM), Price Field Office, and the Manti-La Sal and Fishlake National Forests announce their intent to prepare an EIS and are soliciting public comments regarding issues and resource information on the potential impacts of a proposal to mine Federal coal, using underground methods with limited surface facilities, in the vicinity of Greens Hollow, Utah as requested by Ark Land Company in LBA case number UTU–84102 and in conformance with the provisions of 43 Code of Federal Regulations (CFR) 3425.1.

DATES: This notice initiates the public scoping process. Comments concerning the scope of the analysis must be received within 45 days of publication in the **Federal Register**. The draft EIS is expected in June of 2008 and the final EIS is expected in November of 2008.

ADDRESSES: Send written comments to Bureau of Land Management, Attn: Steve Rigby, Price Field Office, 125 South 600 West, Price, Utah 84501. Written comments may also be hand-delivered to the Price Field Office or sent by facsimile to 435–636–3657. Comments may be sent electronically to *UT_Pr_Comments2@blm.gov* (please reference Greens Hollow Coal Lease Tract EIS in the subject field).

FOR FURTHER INFORMATION CONTACT: Steve Rigby, Project Manager, BLM Price Field Office, 125 South 600 West, Price, Utah 84501 or phone 435–636–3604.

SUPPLEMENTARY INFORMATION: The proposed Greens Hollow coal lease tract is located on the Manti-La Sal and Fishlake National Forests on the southern end of the Wasatch Plateau, Wasatch Plateau coal field, in the Wasatch Plateau Known Recoverable Coal Resource Area (KRCRA). The surface and coal resources are both federally owned. The Manti-La Sal and Fishlake National Forests administer the surface resources, while the BLM administers the subsurface coal resources.

The Greens Hollow coal lease tract is located in the Muddy Creek and North Fork Quitchupah Creek drainages. The area is approximately 10.5 air miles west of the town of Emery, Utah or 5 miles north of the SUFCO mine portal in Convulsion Canyon. The final coal lease tract, as amended by the Tract Delineation Team, encompasses 6,334 acres of Federal coal estate. Most of the proposed lease is on the Manti-La Sal National Forest (approximately 6,253 acres), while a small part along the southern edge of the tract is on the Fishlake National Forest (approximately 81 acres). A map of the proposed lease tract is available at *http://cq.blm.gov/author/ut/en/fo/price/energy/Coal.html*.

Coal reserves in the Greens Hollow coal lease tract are estimated at 73 million minable tons of coal. Ark Land Company has applied to the BLM to lease the coal reserves to increase the production life of their existing SUFCO Mine complex. The tract lies immediately adjacent to and north and west of the existing SUFCO Mine. If Ark Land Company obtains the tract, it would be mined by long-wall methods through underground workings in their existing permit area. Existing portal facilities in the SUFCO mine complex would be used. New surface facilities would include two new vent shafts, a power line to one of the shafts, and exploratory drill holes. The analysis of

impacts will be prepared assuming mining would be done through the SUFCO mine. Because the lease offering would be by competitive bid, if a company other than Ark Land were the successful bidder, the adequacy of the EIS would be re-evaluated to determine if it could be used as the basis for mining plan approval.

The Greens Hollow EIS will be consistent with the Manti-La Sal and Fishlake National Forests Land and Resource Management Plans (Forest Plans). The Forest Plans provide the overall guidance (Goals, Objectives, Standards, and Management Area Direction) to achieve the Desired Future Condition for the area being analyzed, and contain specific management area prescriptions for each Forest. The proposed lease tract is in a management area that is available for further consideration for coal leasing. The Forest Service and BLM have determined that data are available to meet the Data Adequacy Standards for Federal Coal Leasing, Uinta-Southwestern Utah Coal Region.

The Greens Hollow coal tract falls within the Muddy Creek coal tract and a 2-mile buffer, for which three years of field data were collected and a technical analysis of potential effects to resources present in the tract were completed in anticipation of a mining proposal. In 2004 the Forest Service initiated the preparation of an EIS for the Muddy Creek tract. Public scoping was conducted from March 5, 2004 through April 12, 2004 and a total of 10 responses were received. Based on the scoping comments and internal agency review, four resources were identified for detailed analysis in the Muddy Creek EIS: water resources, wildlife and wildlife habitat, vegetation, and cultural/paleontological resources. Previously collected data will be reviewed and updated to ensure the data remain valid for the Greens Hollow analysis.

Purpose and Need for Action

The purpose of the Proposed Action is to provide appropriate opportunities for leasing and development of Federal coal resources (USDA–FS 1986) under the Manti-La Sal and Fishlake National Forests, and to make cleared tracts available for leasing, subject to the mitigation requirements determined through multiple-use management and environmental review.

Ark Land Company, as the lease applicant, has expressed the need to obtain rights to additional minable coal in order to extend the life of the SUFCO Mine by approximately 10 years, maintain production, remain competitive in the current coal market, and to maintain current coal contracts.

Proposed Action

The proposed action would offer the Greens Hollow Coal Lease Tract for competitive leasing. Technical data and analysis would be reviewed to determine if lease stipulations would be needed to protect non-mineral resources consistent with BLM and Forest Service policies and Forest Plan Standards/Guidelines and Objectives.

Possible Alternatives

All of the alternatives and options may not be known until after data collection and completion of the analysis. However, the EIS would likely consider the following alternatives.

Alternative 1 (No Action)—The no action alternative will provide a baseline for evaluating the effects of the action alternatives. Under this alternative the lease tract would not be offered for leasing at this time and there would be no mining within the tract.

Alternative 2—Under this alternative, the tract would be offered for competitive leasing, as delineated by the Tract Delineation Team, with BLM standard lease terms and conditions only. No special coal lease stipulations would be included in the lease to be offered.

Alternative 3—Under this alternative, the tract would be offered for competitive leasing, as delineated, with BLM standard lease terms and conditions and special stipulations to protect non-mineral resources and uses.

Other Action Alternatives—Other alternatives may be developed, as needed, to address social and environmental issues or opportunities.

Lead and Cooperating Agencies

The Bureau of Land Management, Price Field Office, and the Forest Service, Manti-La Sal and Fishlake National Forests, will be joint lead agencies for this project. The Office of Surface Mining (OSM) will participate as a cooperating agency.

Responsible Official

The responsible official for the Bureau of Land Management is Selma Sierra, Utah State Director, Bureau of Land Management, 440 West 200 South, Suite 500, Salt Lake City, Utah 84145–0155. The responsible officials for the Forest Service are Howard Sargent, Forest Supervisor, Manti-La Sal National Forest, 599 W. Price River Drive, Price, Utah 84501, and Mary Erickson, Forest Supervisor, Fishlake National Forest, 115 East 900 North, Richfield, Utah 84701.

Nature of Decision To Be Made

In accordance with the Mineral Leasing Act of 1920, as amended, the Utah State Director of the BLM will decide whether or not to offer the tract for competitive leasing and under what terms, conditions, and stipulations.

In accordance with the Coal Leasing Amendments Act of 1975, which amended the Mineral Leasing Act of 1920, the Forest Supervisors, Manti-La Sal and Fishlake National Forests, will decide whether or not to consent to leasing by the Bureau of Land Management. If they consent to leasing, they will identify special coal lease stipulations needed to protect non-mineral resources.

Scoping Process

This notice of intent in the **Federal Register** initiates the scoping process for the Greens Hollow Coal Lease Tract Environmental Impact Statement. Agency and public scoping comments guide the development of the EIS. It is important that those interested in this proposed action participate at this time. Scoping notification is also given in the *Sun Advocate* and *Richfield Reaper*, the newspapers of record. In addition, a public notice will be published in the *Emery County Progress* and the *Salina Sun* and mailed to potentially interested parties. Interested parties are invited to submit comments as outlined above. To be most helpful, your comments should be as specific as possible.

The lead agencies are seeking information and comments from Federal, State, and local agencies as well as individuals and organizations that may be interested in, or affected by, the proposed action. The BLM and Forest Service invite written comments and suggestions on issues related to the proposal and the area being analyzed. Information received will be used in preparation of the draft EIS and final EIS. No public meetings are currently planned.

Comments, including names and addresses of respondents, will be available for public review at the BLM Price Field Office, and will be subject to disclosure under the Freedom of Information Act (FOIA). Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to

do so. All submissions from organizations and businesses, or from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

A draft EIS will be prepared for public review and comment. The comment period on the draft EIS will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**. It is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Bureau of Land Management at a time when it can meaningfully consider them and respond to them in the final EIS.

To assist the agencies in identifying and considering issues and concerns on the proposed action, comments on the draft EIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft EIS or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

The lead agencies believe, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft EISs must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft EIS stage but that are not raised until after completion of the final EIS may be waived or disregarded by the courts. *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Cir. 1986); and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980).

(Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21; BLM/DOI NEPA Handbook 516 DM).

Preliminary Issues

Issues and alternatives to be evaluated in the analysis for the Greens Hollow coal lease tract will be determined through public scoping. The major issues are expected to include water resources, wildlife and wildlife habitat, vegetation, cultural/paleontological resources, employment in the local area, and economic viability of the local and regional areas.

Permits or Licenses Required

The operator must obtain a permit from the Secretary of the Interior prior to commencing mining, contingent upon review and acceptance of the mining and reclamation plan in accordance with Surface Mining Control and Reclamation Act of 1977 (SMCRA) and the requirements of 30 CFR 700 to end.

Dated: January 29, 2008.

Selma Sierra,

Utah State Director, BLM.

Dated: January 29, 2008.

Howard Sargent,

Forest Supervisor, Manti-La Sal National Forest.

[FR Doc. E8–2557 Filed 2–11–08; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF THE INTERIOR

National Park Service

Boston Harbor Islands National Recreation Area Advisory Council; Notice of Public Meeting

AGENCY: Department of the Interior, National Park Service, Boston Harbor Islands National Recreation Area.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given that a meeting of the Boston Harbor Islands National Recreation Area Advisory Council will be held on Wednesday, March 5, 2008, at 6 p.m. to 8 p.m. at University of Massachusetts—Boston, 100 Morrissey Boulevard, Campus Center, 3rd floor Bayview Room, Boston, MA.

This will be the annual meeting of the Council. The agenda will include a presentation on the development of a new guide book: *Discovering the Boston Harbor Islands*, membership review and election of officers, ''park report card'' update and public comment.

The meeting will be open to the public. Any person may file with the Superintendent a written statement concerning the matters to be discussed. Persons who wish to file a written statement at the meeting or who want further information concerning the meeting may contact Superintendent Bruce Jacobson at (617) 223–8667.

DATE: March 5, 2007 at 6 p.m.

ADDRESSES: University of Massachusetts—Boston, 100 Morrissey Boulevard, Campus Center, 3rd floor Bayview Room, Boston, MA.

FOR FURTHER INFORMATION CONTACT: Superintendent Bruce Jacobson, (617) 223–8667.

SUPPLEMENTARY INFORMATION: The Advisory Council was appointed by the Director of National Park Service pursuant to Public Law 104–333. The 28 members represent business, educational/cultural, community and environmental entities; municipalities surrounding Boston Harbor; Boston Harbor advocates; and Native American interests. The purpose of the Council is to advise and make recommendations to the Boston Harbor Islands Partnership with respect to the development and implementation of a management plan and the operation of the Boston Harbor Islands NRA.

Dated: January 14, 2008.

Bruce Jacobson,

Superintendent, Boston Harbor Islands NRA.

[FR Doc. E8–2561 Filed 2–11–08; 8:45 am]

BILLING CODE 4310–86–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Long-Term Experimental Plan for the Operation of Glen Canyon Dam and Other Associated Management Activities

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: In a **Federal Register** notice published on November 6, 2006 (71 FR 64982–64983), and pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, as amended, and 40 CFR 1508.22, the Department of the Interior, acting through the Bureau of Reclamation (Reclamation), provided notice of its intent to prepare an environmental impact statement (EIS) and conduct public scoping meetings for the adoption of a Long-Term Experimental Plan for the operation of Glen Canyon Dam and other associated management activities. This **Federal Register** notice provides updated information and additional background on the status and development of the Long-Term Experimental Plan, as well as information regarding shorter term proposed flow experiments related to the operation of Glen Canyon Dam.

FOR FURTHER INFORMATION: Dennis Kubly, Bureau of Reclamation, telephone (801) 524–3715; faxogram (801) 524–3858; e-mail at *GCDExpPlan@uc.usbr.gov.*

SUPPLEMENTARY INFORMATION: In a **Federal Register** notice published on November 6, 2006 (71 FR 64982–64983),

and pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, as amended, and 40 CFR 1508.22, the Department of the Interior, acting through Reclamation, provided notice of its intent to prepare an EIS and conduct public scoping meetings for the adoption of a Long-Term Experimental Plan for the operation of Glen Canyon Dam and other associated management activities.

In a **Federal Register** notice published on December 12, 2006, (71 FR 74556–74558), Reclamation provided notice of public scoping meetings on the adoption of a Long-Term Experimental Plan for the operation of Glen Canyon Dam and other associated management activities. Accordingly, public scoping meetings were held in December 2006 and January 2007. Reclamation published a March 2007 scoping report following the conclusion of the scoping process. This report is available on Reclamation's internet site at: *http://www.usbr.gov/uc/rm/gcdltep/scoping/FinalScopingReport.pdf.*

During 2006 and 2007, a significant volume of sediment has been carried by storms into the mainstem of the Colorado River below Glen Canyon Dam and sediment retention in the Grand Canyon below Glen Canyon Dam was higher than anticipated, leading to the largest accumulation of sediment in this reach of the Colorado River since 1998.

During this period, important new information has become available regarding the stabilizing and improving status of the endangered humpback chub. As a result, in December 2007, Reclamation re-initiated Endangered Species Act Section 7 consultation with the U.S. Fish and Wildlife Service on the operation of Glen Canyon Dam. Reclamation's December 2007 Biological Assessment filed with the U.S. Fish and Wildlife Service is available on Reclamation's Internet site at: *http://www.usbr.gov/uc/envdocs/ba/gc-ExpFlow/2007BA.pdf.*

The Section 7 consultation is based on a proposed short-term set of experimental flow actions to be initiated beginning in March 2008 to, in part, capitalize on a unique experimental opportunity that will utilize the recent high sediment input to the Grand Canyon. A proposed March 2008 high-flow release would build on knowledge gained through previous high flow experiments in 1996 and 2004. Beginning in September 2008, Reclamation proposes to initiate steady flow operations for a period of two months (September–October) during each of the next five years (2008 through 2012). These proposed steady flow releases would build on knowledge gained through previous steady flow experiments in 2000. These experimental high and steady flows have been designed and proposed to assist in—and assess the long term benefits of—the conservation of endangered humpback chub and fine sediment along the Colorado River downstream of Glen Canyon Dam.

As of the date of this **Federal Register** notice, the U.S. Fish and Wildlife Service is preparing a Biological Opinion on the proposed short-term experimental flow actions, and Reclamation is preparing an Environmental Assessment on the proposed action. A final decision on whether to conduct the proposed experimental flow actions is expected to be made in February 2008, after appropriate environmental compliance activities are complete. After completion of these ongoing environmental compliance activities, Reclamation will reassess the proposed Long-Term Experimental Plan and any other associated environmental compliance activities. The Long-Term Experimental Plan approach will then be updated to integrate any decisions that are reached regarding Reclamation's proposed short-term experimental flow actions.

Dated: February 4, 2008.

Larry Walkoviak,

Regional Director, UC Region, Bureau of Reclamation.

[FR Doc. E8–2534 Filed 2–11–08; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection for 1029–0067

AGENCY: Office of Surface Mining Reclamation and Enforcement, Department of the Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request renewed authority for the collection of information for 30 CFR part 705 and the Form OSM–23, Restriction on financial interests of State employees.

DATES: Comments on the proposed information collection must be received by April 14, 2008, to be assured of consideration.

ADDRESSES: Comments may be mailed to John A. Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave., NW., Room 202—SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtrelease@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection requests, explanatory information and related forms, contact John A. Trelease, at (202) 208–2783. You may also review the collection request at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8 (d)]. This notice identifies an information collection that OSM will be submitting to OMB for approval. This collection is contained in 30 CFR part 705 and the Form OSM–23, Restriction on financial interests of State employees. OSM will request a 3-year term of approval for this information collection activity.

Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection request to OMB.

The following information is provided for the information collection: (1) Title of the information collection; (2) OMB control number; (3) summary of the information collection activity; and (4) frequency of collection, description of the respondents, estimated total annual responses, and the total annual reporting and recordkeeping burden for the collection of information.

Title: Restrictions on financial interests of State employees, 30 CFR 705.

OMB Control Number: 1029–0067.

Summary: Respondents supply information on employment and financial interests. The purpose of the collection is to ensure compliance with section 517(g) of the Surface Mining control and Reclamation Act of 1977, which placed an absolute prohibition on

having a direct or indirect financial interest in underground or surface coal mining operations.

Bureau Form Number: OSM–23.

Frequency of Collection: Entrance on duty and annually.

Description of Respondents: Any State regulatory authority employee or member of advisory boards or commissions established in accordance with State law or regulation to represent multiple interests who performs any function or duty under the Surface Mining Control and Reclamation Act.

Total Annual Responses: 3,540

Total Annual Burden Hours: 1,184.

Dated: February 1, 2008.

John R. Craynon,

Chief, Division of Regulatory Support.

[FR Doc. 08–598 Filed 2–11–08; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Modification In United States V. East Kentucky Power Cooperative, Inc. Under the Clean Air Act

Under 28 CFR 50.7, notice is hereby given that on February 5, 2008, a proposed modification (''Modification'') to a consent decree (''Consent Decree'') between East Kentucky Power Cooperative, Inc. (''EKPC'') and the United States, Civil Action No. 04–34–KSF, was lodged with the United States District Court for the Eastern District of Kentucky.

The original Consent Decree was lodged with the United States District Court for the Eastern District of Kentucky on July 2, 2007, and entered by the Court on September 24, 2007. The Consent Decree resolved claims asserted by the United States against EKPC pursuant to Sections 113(b) and 167 of the Clean Air Act (the ''Act''), 42 U.S.C. 7413(b) and 7477, seeking injunctive relief and the assessment of civil penalties for EKPC's violations of:

(a) The Prevention of Significant Deterioration (''PSD'') provisions in Part C of Subchapter I of the Act, 42 U.S.C. 7470–92;

(b) The New Source Performance Standards (''NSPS'') provisions of the Act, 42 U.S.C. 7411;

(c) Title V of the Act, 42 U.S.C. 7661, *et seq.*; and

(d) The federally-enforceable State Implementation Plan (''SIP'') developed by the Commonwealth of Kentucky.

See 72 FR 37797 (July 11, 2007).

EKPC operates three coal-fired power plants in Kentucky: the Spurlock Plant, located near Maysville, Kentucky, the Dale Plant, located near Winchester, Kentucky, and the Cooper Plant, located near Somerset, Kentucky. The complaint filed by the United States alleged that EKPC modified Spurlock Unit 2 and Dale Units 3 and 4 without complying with PSD (including the requirements to first obtain a PSD permit authorizing the modifications and to install and operate the best available technology to control emissions of sulfur dioxide (''SO_2''), nitrogen oxides (''NO_X''), and/or particulate matter (''PM'')), and modified Dale Units 3 and 4 without complying with NSPS. The Complaint also alleged that EKPC violated Title V of the Act by failing to include the PSD and NSPS requirements triggered by its modifications in its Title V operating permits for the Spurlock and Dale plants. Finally, the Complaint alleged that EKPC illegally operated Spurlock Unit 2 at heat input capacities that were higher than allowed by its operating permit.

The Consent Decree entered by the Court on September 24, 2007 requires, inter alia, that EKPC reduce SO_2, NO_X and PM emissions at its plants through the installation and operation of state-of-the-art pollution control technologies and/or the retirement or re-powering of certain units. The proposed Modification would extend by up to 60 days the time for EKPC to comply with the Consent Decree's 30-day rolling average emission rates for NO_X applicable to Spurlock Unit 1. The extension relates to a transformer failure at the Spurlock Plant that altered EKPC's scheduled installation of a third catalyst layer for selective catalytic reduction (''SCR'') controls at Spurlock Unit 1, which resulted in EKPC's inability to operate the SCR in time to meet the applicable 30-day rolling average emission rates for NO_X. The Modification also requires EKPC to mitigate the effect of the excess emissions caused by the delay, by retiring NO_X allowances equal to the amount of excess emissions, plus a premium of ten percent.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Modification. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *East Kentucky Power Cooperative*, D.J. Ref. No. 90–5–2–1–08085.

The Modification may be examined at the Office of the United States Attorney, Eastern District of Kentucky, 260 West Vine Street, Suite 300, Lexington, Kentucky, 40507–1612, and at U.S. EPA Region IV, 61 Forsyth Street, SW., Atlanta, Georgia, 30303–8960. During the public comment period, the Modification may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html*. A copy of the Modification may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $1.75 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

W. Benjamin Fisherow,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. E8–2493 Filed 2–11–08; 8:45 am]

BILLING CODE 4410–CW–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA'')

Under the policy set out at 28 CFR 50.7, notice is hereby given that on February 7, 2008, the United States lodged with the United States District Court for the District of Montana a proposed consent decree (''Consent Decree'') in the case of *United States* v. *Atlantic Richfield Company, et al.*, Civil Action No. CV–89–39–BU–SEH. The Consent Decree pertains primarily to the Clark Fork River Operable Unit (the ''Clark Fork Site'') in southwestern Montana. The settlement would resolve the claims brought by the United States against the Atlantic Richfield Company under Section 107 of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (''CERCLA''), 42 U.S.C. 9607, for the recovery of costs incurred and to be incurred in responding to releases and threatened releases of hazardous substances at the Clark Fork Site. Under the terms of the proposed Consent Decree, Atlantic

Richfield will provide funding to implement EPA's cleanup plan for the Clark Fork Site and reimburse costs incurred by EPA in responding to contamination at the Clark Fork Site. The proposed Consent Decree will also, among other things, require Atlantic Richfield to: reimburse the U.S. National Park Service for costs incurred by the National Park Service in responding to contamination at the Grant-Kohrs Ranch National Historic Site, which is a National Park within the geographic boundary of the Clark Fork Site; pay the National Park Service and the U.S. Bureau of Land Management for natural resource damages restoration work at the Grant Kohrs Ranch and at certain property owned by the U.S. Bureau of Land Management within the Clark Fork Site; and pay the State of Montana for restoration work that the State plans to conduct at the Clark Fork Site and at two other Superfund sites in and near Anaconda and Butte, Montana.

The Department of Justice will receive comments relating to the proposed Consent Decree for a period of sixty (60) days from the date of this publication. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Atlantic Richfield*, DJ Ref. No. 90–11–2–430.

The proposed Consent Decree may be examined at the office of the United States Attorney for the District of Montana, 2929 Third Avenue North, Suite 400, Billings, Montana 59101, and at the U.S. EPA Region VIII Montana Office, Federal Building, 10 West 15th Street, Suite 3200, Helena, Montana 59624. During the public comment period, the proposed Consent Decree may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html*. In addition, a copy of the Consent Decree may be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check payable to the U.S. Treasury in the amount of $41.75 (25 cents per page reproduction cost) for the Consent Decree, plus $188.00 if you want a copy of the appendices to the Consent Decree and $8.75 for a copy of a related consent decree between the State of Montana and the Atlantic Richfield Company regarding the Clark Fork, Anaconda, and Butte Sites.

Robert Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. E8–2547 Filed 2–11–08; 8:45 am]

BILLING CODE 4410–CW–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[OMB Number 1117–0003]

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60-Day Notice of Information Collection Under Review; ARCOS Transaction Reporting—DEA Form 333.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted until April 14, 2008. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* ARCOS Transaction Reporting—DEA Form 333.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:

Form Number: DEA Form 333.

Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract:

Primary: Business or other for-profit.

Other: None.

Abstract: Controlled substances Manufacturers and distributors must report acquisition/distribution transactions to DEA to comply with Federal law and international treaty obligations. This information helps to ensure a closed system of distribution for these substances.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: DEA estimates that 1,173 respondents, with 7,768 responses annually to this collection. DEA estimates that it takes 1 hour to complete the form.

(6) An estimate of the total public burden (in hours) associated with the collection: DEA estimates this collection has a public burden of 7,768 hours annually.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: February 6, 2008.

Lynn Bryant,

Department Clearance Officer, PRA, Department of Justice.

[FR Doc. E8–2519 Filed 2–11–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[OMB Number 1117–0001]

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60–Day Notice of Information Collection Under Review; Report of Theft or Loss of Controlled Substances—DEA Form 106.

The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted until April 14, 2008. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Report of Theft or Loss of Controlled Substances (DEA Form 106).

(3) Agency form number, if any, and the applicable component of the Department sponsoring the collection:

Form number: DEA Form 106.

Component: Office of Diversion Control, Drug Enforcement Administration, Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract:

Primary: Business or other for-profit.

Other: Not-for-profit, State, local or tribal government.

Abstract: Title 21 CFR, 1301.74(c) & 1301.76(b) require DEA registrants to complete and submit DEA–106 upon discovery of a theft or significant loss of controlled substances. This provides accurate accountability and allows DEA to monitor substances diverted for illicit purposes.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: DEA estimates that 6,250 registrants submit 9,500 forms annually for this collection, taking .5 hours (30 minutes) to complete each form.

(6) An estimate of the total public burden (in hours) associated with the collection: 4,750 annual burden hours.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: February 6, 2008.

Lynn Bryant

Department Clearance Officer, PRA Department of Justice.

[FR Doc. E8–2520 Filed 2–11–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment and Training Administration

Proposed Information Collection Request for the Unemployment Insurance (UI) Data Validation (DV) Program; Comment Request

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Notice.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, the Department of Labor (Department) conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that the requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the **ADDRESSES** section of this notice or by accessing: *http://www.doleta.gov/OMBCN/OMBControlNumber.cfm.*

DATES: Submit comments to the office listed in the **ADDRESSES** section below on or before April 14, 2008.

ADDRESSES: Submit comments to Burman Skrable, Office of Workforce Security, Employment and Training Administration, U.S. Department of Labor, Room S–4522, 200 Constitution Avenue, NW., Washington, DC 20210, telephone: 202–693–3197 (this is not a toll-free number), fax: 202–693–3975, e-mail: *skrable.burman@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. *Background:* Section 303(a)(6) of the Social Security Act specifies that the Secretary of Labor will not certify State UI programs to receive administrative grants unless the State's law includes provisions for—

Making of such reports * * * as the Secretary of Labor may from time to time require, and compliance with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports.

The Department considers data validation one of those ''provisions * * * necessary to assure the correctness and verification'' of the reports it requires.

The Government Performance and Results Act of 1993 (GPRA) requires Federal agencies to develop annual and strategic performance plans that establish performance goals, have concrete indicators of the extent that goals are achieved, and set performance targets. Each year, the agency is to issue a report that ''evaluate[s] the performance plan for the current fiscal year relative to the performance achieved toward the performance goals

in the fiscal year covered by the report.'' Section 1116(d)(2) of OMB Circular A–11, which implements the GPRA process, cites the Reports Consolidation Act of 2000 to emphasize the need for data validation by requiring that the agency's annual performance report ''contain an assessment of the completeness and reliability of the performance data included in it [that] * * * describes any material inadequacies in the completeness and reliability of the data.'' (OMB Circular A–11, section 230.2(f).) The President's Management Agenda has also emphasized the importance of complete information for program monitoring and improving program results to improve the management and performance of the Federal government.

The UI DV system checks the validity of 1,275 data elements reported on 12 benefits reports and one tax report. The Department uses many of these elements for key performance measures as well as for allocating administrative funds among states, and for critical economic reports.

II. *Desired Focus of Comments:* Currently, the Department is soliciting comments concerning the extension of the UI DV Program which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

III. *Current Actions:* The validation process assesses the validity (accuracy) of the counts of transactions or measurements of status as follows. In the validation process, guided by a detailed handbook, the state first constructs extract files containing all pertinent individual transactions for the desired report period to be validated. Each transaction contains the necessary characteristics or dimensions that enable it to be summed into an independent recount of what the state has already reported. Standardized software edits the extract file, e.g., to remove duplicate transactions, then aggregates the transactions to produce an independent reconstruction or ''validation count'' of the reported figure. The reported count is considered valid by this ''quantity'' validation test if it is within ±2% of the validation count (±1% for a GPRA-related element). The software also draws samples of most transaction types from the extract files; guided by a state-specific handbook, the validators review these against documentation in the state's management information system to determine whether the transactions in the extract file are supported by system documentation and thus that the validation count can be trusted as accurate. The extract files are considered to pass this ''quality'' review if random samples indicate that no more than 5% of the records contain errors.

Beginning in FY 2008 and beyond, all states will be required to conduct a complete validation every three years. There are two exceptions to this rule: (1) Groups of reported counts that are summed for purposes of making a Pass/Fail determination and do not pass validation by being within ±2% of the reconstructed counts (±1% in the case of report elements used to calculate GPRA measures) must be revalidated within one year; the same is true for random samples that show that the underlying population from which they are drawn contains more than 5% of its transactions in error; and (2) all samples and counts used for GPRA measures must be validated annually regardless of whether they pass validity standards or not.

Type of Review: Extension without change.

Agency: Employment and Training Administration (ETA).

Title: Unemployment Insurance Data Validation Program.

OMB Number: 1205–0431.

Agency Number: ETA Handbook 361.

Recordkeeping: States are required to retain validation results and supporting documentation for three years to support an audit.

Affected Public: State Workforce Agencies (SWAs).

Total Respondents: 53.

Frequency: Annual.

Total Responses: 53 per year.

Estimated Time per Response: 550 hours.

Total Burden Hours: 29,150 hours.

Total Burden Cost (capital/startup): N/A.

Total Burden Cost (operating/maintaining): $1,060,769.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of the information collection request; they will also become a matter of public record.

Dated: February 6, 2008.

Cheryl Atkinson,

Administrator, Office of Workforce Security, Washington, DC.

[FR Doc. E8–2555 Filed 2–11–08; 8:45 am]

BILLING CODE 4510–FW–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (08–013)]

NASA Advisory Council; Science Committee; Planetary Science Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: The National Aeronautics and Space Administration (NASA) announces a meeting of the Planetary Science Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The Meeting will be held for the purpose of soliciting from the scientific community and other persons scientific and technical information relevant to program planning.

DATES: Monday, March 3, 2008, 8:30 a.m. to 5:30 p.m., and Tuesday, March 4, 2008, 8:30 a.m. to 5 p.m.

ADDRESSES: The Carnegie Institution of Washington, Greenewalt Lecture Hall, 5241 Broad Band Road, NW., Washington, DC 20015.

FOR FURTHER INFORMATION CONTACT: Ms. Marian Norris, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–4452, fax (202) 358–4118, or *mnorris@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. The agenda for the meeting includes the following topics:

—Planetary Science Division Update.
—Analysis Group and Management Operations Working Group Reports.
—Lunar Architecture Team 2 Study.
—Alternative Launch Vehicles Study.

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a visitor's register.

Dated: February 5, 2008.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. E8–2513 Filed 2–11–08; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

Biweekly Notice; Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. The Act requires the Commission publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from January 17, 2008, to January 30, 2008. The last biweekly notice was published on (73 FR 5215).

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rulemaking, Directives and Editing Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, person(s) may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request via electronic submission through the NRC E-Filing system for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner/requestor intends to rely in proving the contention at the hearing. The petitioner/requestor must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner/requestor intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the

applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner/ requestor to relief. A petitioner/ requestor who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for hearing or a petition for leave to intervene must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated in August 28, 2007, (72 FR 49139). The E-Filing process requires participants to submit and serve documents over the internet or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least five (5) days prior to the filing deadline, the petitioner/ requestor must contact the Office of the Secretary by e-mail at *hearingdocket@nrc.gov*, or by calling (301) 415–1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances in which the petitioner/requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each petitioner/ requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at *http://www.nrc.gov/site-help/e-submittals/install-viewer.html.* Information about applying for a digital ID certificate is available on NRC's public website at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.*

Once a petitioner/requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the filer submits its documents through EIE. To be timely, an electronic filing must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/ petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically may seek assistance through the ''Contact Us'' link located on the NRC website at *http://www.nrc.gov/site-help/e-submittals.html* or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397–4209 or locally, (301) 415–4737.

Participants who believe that they have a good cause for not submitting documents electronically must file a motion, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville, Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Non-timely requests and/or petitions and contentions will not be entertained absent a determination by the Commission, the presiding officer, or the Atomic Safety and Licensing Board that the petition and/or request should be granted and/or the contentions should be admitted, based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)-(viii). To be timely, filings must be submitted no later than 11:59 p.m. Eastern Time on the due date.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd.nrc.gov/EHD_Proceeding/home.asp*, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to this amendment action, see the application for amendment which is available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the ADAMS Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html*. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by email to *pdr@nrc.gov*.

AmerGen Energy Company, LLC, Docket No. 50–461, Clinton Power Station, Unit No.1, DeWitt County, Illinois

Date of amendment request: June 21, 2007.

Description of amendment request: A change is proposed to the technical specifications (TSs) of Clinton Power Station, Unit No. 1 (CPS), consistent with TS Task Force (TSTF) change TSTF–423 to the standard technical specifications (STSs) for boiling-water reactor (BWR) plants to allow, for some systems, entry into hot shutdown rather than cold shutdown to repair equipment, if risk is assessed and managed consistent with the program in place for complying with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.65(a)(4). The proposed amendment would modify the TS to risk-informed requirements regarding selected required action end states provided in TSTF–423, Revision 0, ''Technical Specification End States, NEDC–32988–A.''

The CPS has reviewed the proposed no significant hazards consideration (NSHC) determination published on March 23, 2006, (71 FR 14743) as part of the consolidated line item improvement process and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. The licensee has affirmed the applicability of the following NSHC determination in its application.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated

The proposed change allows a change to certain required end states when the TS Completion Times for remaining in power operation will be exceeded. Most of the requested technical specification (TS) changes are to permit an end state of hot shutdown (Mode 3) rather than an end state of cold shutdown (Mode 4) contained in the current TS. The request was limited to: (1) Those end states where entry into the shutdown mode is for a short interval, (2) entry is initiated by inoperability of a single train of equipment or a restriction on a plant operational parameter, unless otherwise stated in the applicable technical specification, and (3) the primary purpose is to correct the initiating condition and return to power operation as soon as is practical. Risk insights from both the qualitative and quantitative risk assessments were used in specific TS assessments. Such assessments are documented in Section 6 of GE NEDC–32988, Revision 2, ''Technical Justification to Support Risk Informed Modification to Selected Required Action End States for BWR Plants.'' They provide an integrated discussion of deterministic and probabilistic issues, focusing on specific technical specifications, which are used to support the proposed TS end state and associated restrictions. The [NRC] staff finds that the risk insights support the conclusions of the specific TS assessments. Therefore, the probability of an accident previously evaluated is not significantly increased, if at all. The consequences of an accident after adopting proposed TSTF–423, are no different than the consequences of an accident prior to adopting TSTF–423. Therefore, the consequences of an accident previously evaluated are not significantly affected by this change. The addition of a requirement to assess and manage the risk introduced by this change will further minimize possible concerns. Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From Any Previously Evaluated.

The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed). If risk is assessed and managed, allowing a change to certain required end states when the TS Completion Times for remaining in power operation are exceeded, i.e., entry into hot shutdown rather than cold shutdown to repair equipment, will not introduce new failure modes or effects and will not, in the absence of other unrelated failures, lead to an accident whose consequences exceed the consequences of accidents previously evaluated. The addition of a requirement to assess and manage the risk introduced by this change and the commitment by the licensee to adhere to the guidance in TSTF–IG–05–02, Implementation Guidance for TSTF–423, Revision 0, ''Technical Specifications End States, NEDC–32988–A,'' will further minimize possible concerns. Thus, this change does not create the possibility of a new or different kind of accident from an accident previously evaluated.

Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety

The proposed change allows, for some systems, entry into hot shutdown rather than cold shutdown to repair equipment, if risk is assessed and managed. The BWROG's risk assessment approach is comprehensive and follows [NRC] staff guidance as documented in RGs [Regulatory Guides] 1.174 and 1.177. In addition, the analyses show that the criteria of the three-tiered approach for allowing TS changes are met. The risk impact of the proposed TS changes was assessed following the three-tiered approach recommended in RG 1.177. A risk assessment was performed to justify the proposed TS changes. The net change to the margin of safety is insignificant. Therefore, this change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the analysis adopted by the licensee and based on this review, it appears that the standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the requested amendments involve no significant hazards consideration.

Attorney for licensee: Mr. Bradley J. Fewell, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.

NRC Branch Chief: Russell Gibbs.

Nebraska Public Power District, Docket No. 50–298, Cooper Nuclear Station, Nemaha County, Nebraska

Date of amendment request: January 14, 2008.

Description of amendment request: The proposed amendment would revise the Technical Specification (TS) requirements related to control room envelope habitability in accordance with TS Task Force (TSTF) traveler TSTF–448–A, ''Control Room Habitability,'' Revision 3.

The NRC staff issued a ''Notice of Availability of Technical Specification Improvement to Modify Requirements Regarding Control Room Envelope Habitability Using the Consolidated Line Item Improvement Process'' in the **Federal Register** on January 17, 2007 (72 FR 2022). The notice referenced a model safety evaluation, a model no significant hazards consideration (NSHC) determination, and a model license amendment request published in the **Federal Register** on October 17, 2006 (71 FR 61075). In its application dated January 14, 2008, the licensee affirmed the applicability of the model NSHC determination which is presented below.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of NSHC adopted by the licensee is presented below:

Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated

The proposed change does not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, or configuration of the facility. The proposed change does not alter or prevent the ability of structures, systems, and components (SSCs) to perform their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed change revises the TS for the CRE emergency ventilation system, which is a mitigation system designed to minimize unfiltered air leakage into the CRE and to filter the CRE atmosphere to protect the CRE occupants in the event of accidents previously analyzed. An important part of

the CRE emergency ventilation system is the CRE boundary. The CRE emergency ventilation system is not an initiator or precursor to any accident previously evaluated. Therefore, the probability of any accident previously evaluated is not increased. Performing tests to verify the operability of the CRE boundary and implementing a program to assess and maintain CRE habitability ensure that the CRE emergency ventilation system is capable of adequately mitigating radiological consequences to CRE occupants during accident conditions, and that the CRE emergency ventilation system will perform as assumed in the consequence analyses of design basis accidents. Thus, the consequences of any accident previously evaluated are not increased. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From Any Accident Previously Evaluated

The proposed change does not impact the accident analysis. The proposed change does not alter the required mitigation capability of the CRE emergency ventilation system, or its functioning during accident conditions as assumed in the licensing basis analyses of design basis accident radiological consequences to CRE occupants. No new or different accidents result from performing the new surveillance or following the new program. The proposed change does not involve a physical alteration of the plant (i.e., no new or different type of equipment will be installed) or a significant change in the methods governing normal plant operation. The proposed change does not alter any safety analysis assumptions and is consistent with current plant operating practice. Therefore, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety

The proposed change does not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The proposed change does not affect safety analysis acceptance criteria. The proposed change will not result in plant operation in a configuration outside the design basis for an unacceptable period of time without compensatory measures. The proposed change does not adversely affect systems that respond to safely shut down the plant and to maintain the plant in a safe shutdown condition. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the analysis adopted by the licensee and, based upon this review, it appears that the standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendment involves NSHC.

Attorney for licensee: Mr. John C. McClure, Nebraska Public Power District, Post Office Box 499, Columbus, NE 68602–0499.

NRC Branch Chief: Thomas G. Hiltz.

Pacific Gas and Electric Co., Docket No. 50–133, Humboldt Bay Power Plant (HBPP), Unit 3 Humboldt County, California

Date of amendment request: November 5, 2007.

Description of amendment request: The licensee has proposed an amendment to Facility Operating License No. DPR–7 for HBPP Unit 3 to delete the paragraph 2.C.1 requirement to implement and maintain a physical security plan. In conjunction with this request the licensee is also requesting exemptions from the requirements in 10 CFR 50.54(p) ''Conditions of Licenses'' and 10 CFR 73 ''Physical Protection of Plants and Materials.'' In addition, the licensee is requesting rescission of NRC Order EA–02–077, ''Order for Interim Safeguards and Security Compensatory Measures'' and NRC Order EA–03–099, ''Order for the Implementation of Additional Security Measures Associated with Access Authorization, Fitness for Duty and Behavior Observation.''

The requested license amendment, exemption and rescission would eliminate the security, fitness for duty and access authorization requirements for HBPP Unit 3 after spent nuclear fuel assemblies and fuel fragment containers have been transferred from the Spent Fuel Pool (SFP) to the Humboldt Bay (HB) Independent Spent Fuel Storage Installation (ISFSI).

The licensee will be required to provide protection for the spent fuel in the HB ISFSI in accordance with the HB ISFSI physical security plan approved by NRC License SNM–2514, dated November 17, 2005, to meet the requirements of 10 CFR 72, subpart H, ''Physical Protection.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The structures, systems, and components of the Humboldt Bay Power Plant (HBPP) Unit 3 and the operating procedures for their use are unaffected by the proposed change. The elimination of the security requirements for HBPP Unit 3 does not affect possible initiating events for accidents previously evaluated or alter the configuration or operation of the facility.

The accidents previously evaluated include spent fuel handling accident, Spent Fuel Pool (SFP) rupture, heavy load drop onto fuel in the SFP, uncontrolled release of radioactive liquid radioactive waste, explosions, release of toxic chemicals and fire. None of these accidents are impacted by the elimination of security requirements.

(2) Does the change create the possibility of a new or different kind of accident from any accident evaluated?

Response: No.

The proposed change is security related and has no direct impact on plant equipment or the procedures for operating plant equipment. The safety analysis for the facility remains complete and accurate. There are no physical changes to the facility, and the plant conditions for which the design basis accidents have been evaluated are still valid.

(3) Does the change involve a significant reduction in a margin of safety?

Response: No.

The proposed change is security related and has no direct impact on plant equipment or the procedures for operating plant equipment. There are no changes to the design or operation of the facility.

The assumptions for a fuel handling and other accidents are not affected by the proposed license amendment. Accordingly, neither the design basis nor the accident assumptions in the Defueled Safety Analysis Report nor the Technical Specifications Bases are affected. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ms. Jennifer K. Post, Pacific Gas and Electric Company, 77 Beale Street, B30A, San Francisco, CA.

NRC Branch Chief: Andrew Persinko.

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina Date of Amendment Request: January 17, 2008.

Description of amendment request: The proposed amendments would revise Technical Specification (TS) 3.7.6, ''Control Room Normal and Emergency Air Handling System,'' and TS Section 6.8, ''Procedures and Programs.'' These changes are based on TS Task Force (TSTF) change traveler TSTF–448, Revision 3 that has been approved generically for the Standard Technical Specifications—

Westinghouse Plants, NUREG–1431. The NRC staff issued a notice of availability of a model safety evaluation and model no significant hazards consideration (NSHC) determination for referencing in license amendment applications in the **Federal Register** on January 17, 2007 (72 FR 2022). The licensee affirmed the applicability of the model NSHC determination in its application dated January 17, 2008.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated

The proposed change does not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, or configuration of the facility. The proposed change does not alter or prevent the ability of structures, systems, and components (SSCs) to perform their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits.

The proposed change revises the TS for the CRE [control room envelope] emergency ventilation system, which is a mitigation system designed to minimize unfiltered air leakage into the CRE and to filter the CRE atmosphere to protect the CRE occupants in the event of accidents previously analyzed. An important part of the CRE emergency ventilation system is the CRE boundary. The CRE emergency ventilation system is not an initiator or precursor to any accident previously evaluated.

Therefore, the probability of any accident previously evaluated is not increased. Performing tests to verify the operability of the CRE boundary and implementing a program to assess and maintain CRE habitability ensure that the CRE emergency ventilation system is capable of adequately mitigating radiological consequences to CRE occupants during accident conditions, and that the CRE emergency ventilation system will perform as assumed in the consequence analyses of design basis accidents. Thus, the consequences of any accident previously evaluated are not increased.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From Any Accident Previously Evaluated

The proposed change does not impact the accident analysis. The proposed change does not alter the required mitigation capability of the CRE emergency ventilation system, or its functioning during accident conditions as assumed in the licensing basis analyses of design basis accident radiological consequences to CRE occupants. No new or different accidents result from performing the new surveillance or following the new program. The proposed change does not involve a physical alteration of the plant (i.e., no new or different type of equipment will be installed) or a significant change in the methods governing normal plant operation.

The proposed change does not alter any safety analysis assumptions and is consistent with current plant operating practice.

Therefore, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety

The proposed change does not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The proposed change does not affect safety analysis acceptance criteria. The proposed change will not result in plant operation in a configuration outside the design basis for an unacceptable period of time without compensatory measures. The proposed change does not adversely affect systems that respond to safely shut down the plant and to maintain the plant in a safe shutdown condition. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

Based upon the reasoning presented above and the previous discussion of the amendment request, the requested change does not involve a no significant hazards consideration.

The NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for Licensee: Thomas G. Eppink, South Carolina Electric & Gas Company, Post Office Box 764, Columbia, South Carolina 29218.

NRC Branch Chief: Melanie Wong, Acting Chief.

STP Nuclear Operating Company, Docket Nos. 50–498 and 50–499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: November 8, 2007.

Description of amendment request: The proposed amendments would revise Technical Specification 3/4.8.2, ''DC Sources,'' to modify battery surveillance requirements. Specifically, the proposed changes would allow battery performance discharge testing to be performed while the associated unit is at power.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

• The proposed change[s] [do] not involve a significant increase in the probability or consequences of an accident previously evaluated.

Performance of the surveillance is not an accident initiator. Consequently, the probability of an accident occurring is not affected by [these] proposed change[s]. Accident mitigation will be provided by the redundant channels should an accident occur while a channel is being tested.

The risk-informed configuration management program, as approved in Amendments 179 and 166, effectively manages the availability of required systems, structures, and components to assure there is no significant increase in the probability of an accident. Therefore, the proposed change[s] [do] not involve a significant increase in the probability or consequences of an accident previously evaluated.

• The proposed change[s] [do] not create the possibility of a new or different kind of accident from any previously evaluated.

The proposed change[s] [do] not involve a new mode of operation or design configuration. The only change is in the duration of a battery's unavailability, which is established consistent with the level of associated risk. Therefore, the proposed change[s] [do] not create the possibility of a new or different accident from any accident previously evaluated.

• The proposed change[s] [do] not involve a significant reduction in the margin of safety.

The risk-informed configuration management program assures that adequate margins of safety are maintained. The configuration management program considers cumulative effects of multiple systems and components being out of service. Therefore, the proposed change[s] [do] not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendments involves no significant hazards consideration.

Attorney for licensee: A.H. Gutterman, Esq., Morgan, Lewis & Bockius, 1111 Pennsylvania Avenue, NW., Washington, DC 20004.

NRC Branch Chief: Thomas G. Hiltz.

Wolf Creek Nuclear Operating Corporation, Docket No. 50–482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: January 15, 2008.

Description of amendment request: The proposed amendment would modify the Technical Specification (TS) to establish more effective and appropriate action, surveillance, and administrative requirements related to ensuring the habitability of the control room envelope (CRE) in accordance with Nuclear Regulatory Commission (NRC)–approved TS Task Force (TSTF) Standard Technical Specification

change traveler TSTF–448, Revision 3, ''Control Room Habitability.'' Specifically, the proposed amendment would modify TS 3.7.10, ''Control Room Emergency Ventilation System (CREVS),'' and would establish a CRE habitability (CREH) program in TS Section 5.5, ''Administrative Controls—Programs and Manuals.'' The NRC staff issued a ''Notice of Availability of Technical Specification Improvement to Modify Requirements Regarding Control Room Envelope Habitability Using the Consolidated Line Item Improvement Process'' associated with TSTF–448, Revision 3, in the **Federal Register** on January 17, 2007 (72 FR 2022). The notice included a model safety evaluation, a model no significant hazards consideration (NSHC) determination, and a model license amendment request. In its application dated January 15, 2008, the licensee affirmed the applicability of the model NSHC determination which is presented below.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of NSHC adopted by the licensee is presented below:

Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated

The proposed change does not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, or configuration of the facility. The proposed change does not alter or prevent the ability of structures, systems, and components (SSCs) to perform their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed change revises the TS for the CRE emergency ventilation system, which is a mitigation system designed to minimize unfiltered air leakage into the CRE and to filter the CRE atmosphere to protect the CRE occupants in the event of accidents previously analyzed. An important part of the CRE emergency ventilation system is the CRE boundary. The CRE emergency ventilation system is not an initiator or precursor to any accident previously evaluated. Therefore, the probability of any accident previously evaluated is not increased. Performing tests to verify the operability of the CRE boundary and implementing a program to assess and maintain CRE habitability ensure that the CRE emergency ventilation system is capable of adequately mitigating radiological consequences to CRE occupants during accident conditions, and that the CRE emergency ventilation system will perform as assumed in the consequence analyses of design basis accidents. Thus, the consequences of any accident previously evaluated are not increased. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From Any Accident Previously Evaluated

The proposed change does not impact the accident analysis. The proposed change does not alter the required mitigation capability of the CRE emergency ventilation system, or its functioning during accident conditions as assumed in the licensing basis analyses of design basis accident radiological consequences to CRE occupants. No new or different accidents result from performing the new surveillance or following the new program. The proposed change does not involve a physical alteration of the plant (i.e., no new or different type of equipment will be installed) or a significant change in the methods governing normal plant operation. The proposed change does not alter any safety analysis assumptions and is consistent with current plant operating practice. Therefore, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety

The proposed change does not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The proposed change does not affect safety analysis acceptance criteria. The proposed change will not result in plant operation in a configuration outside the design basis for an unacceptable period of time without compensatory measures. The proposed change does not adversely affect systems that respond to safely shut down the plant and to maintain the plant in a safe shutdown condition. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the analysis adopted by the licensee and, based on this review, it appears that the standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendments involves NSHC.

Attorney for licensee: Terence A. Burke, Associate General Council—Nuclear Entergy Services, Inc., 1340 Echelon Parkway, Jackson, Mississippi 39213.

NRC Branch Chief: Thomas G. Hiltz.

Notice of Issuance of Amendments to Facility Operating Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov.*

Carolina Power & Light Company, Docket Nos. 50–325 and 50–324, Brunswick Steam Electric Plant, Units 1 and 2, Brunswick County, North Carolina

Date of application for amendments: December 21, 2006.

Brief Description of amendments: The amendments change the Technical Specifications (TSs) related to the reactor recirculation system flow balance.

Date of issuance: December 17, 2007.

Effective date: Date of issuance, to be implemented within 60 days.

Amendment Nos.: 244 and 272.

Facility Operating License Nos. DPR–71 and DPR–62: Amendments changed the TSs.

Date of initial notice in ***Federal Register:*** March 13, 2007 (72 FR 11385).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated December 17, 2007.

No significant hazards consideration comments received: No.

Dominion Nuclear Connecticut, Inc., Docket No. 50–336, Millstone Power Station, Unit No. 2 New London County, Connecticut

Date of amendment request: November 8, 2006, as supplemented by letters dated May 4, October 4, and November 27, 2007.

Brief description of amendment: The amendment revises the Millstone Power Station, Unit No. 2 Technical Specifications (TSs) Action and Surveillance Requirements for instrumentation identified in TSs 3.3.1 and 3.3.2. In particular, the amendment adds actions to address the inoperability of one or more automatic bypass removal channels; revises the terminology used in the notation of TS 2.2–1 and 3.3–1 relative to the implementation and automatic removal of certain Reactor Protective System trip bypasses; revises the frequency for performing surveillance of the automatic bypass removal function logic; and incorporates two administrative changes.

Date of issuance: January 29, 2008.

Effective date: As of the date of issuance and shall be implemented within 90 days from the date of issuance.

Amendment No.: 301.

Facility Operating License No. DPR–65: Amendment revised the License and Technical Specifications.

Date of initial notice in ***Federal Register:*** April 24, 2007 (72 FR 20380).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated January 29, 2008.

No significant hazards consideration comments received: No.

Indiana Michigan Power Company, Docket Nos. 50–315, Donald C. Cook Nuclear Plant, Units 1 and 2 (DCCNP–1 and DCCNP–2), Berrien County, Michigan

Date of application for amendments: May 11, 2007.

Brief description of amendments: The amendments revise the DCCNP–1 and DCCNP–2 Technical Specifications to increase the power level at which performance of the trip actuating device operational test (TADOT) of a reactor trip following a turbine trip signal is required. Specifically, the previous Surveillance Requirement 3.3.1.18 required performance of a TADOT of a reactor trip on turbine trip prior to exceeding the P–7 interlock (at approximately 10 percent of the rated thermal power (RTP)) whenever the unit has been in Mode 3, if not performed within the previous 31 days. The amendments replace the ''P–7'' interlock with the ''P–8'' interlock (at approximately 31 percent RTP).

Date of issuance: January 11, 2008.

Effective date: As of the date of issuance, and shall be implemented within 45 days.

Amendment No.: 301 (for DCCNP–1) and 284 (for DCCNP–2).

Facility Operating License Nos. DPR–58 and DPR–74: Amendments revise the Renewed Operating Licenses and Technical Specifications.

Date of initial notice in Federal Register: June 19, 2007 (72 FR 33783).

The Commission's related evaluation of the amendment is contained in a safety evaluation dated January 11, 2008.

No significant hazards consideration comments received: No.

Luminant Generation Company LLC, Docket Nos. 50–445 and 50–446, Comanche Peak Steam Electric Station, Unit Nos. 1 and 2, Somervell County, Texas

Date of amendment request: December 19, 2006, as supplemented by letters dated November 30, and December 6, 2007.

Brief description of amendments: The amendments revise Technical Specifications (TS) 3.7.5, ''Auxiliary Feedwater (AFW) System,'' TS 3.8.1, ''AC [Alternating Current] Sources—Operating,'' TS 3.8.9, ''Distribution Systems—Operating,'' and TS Example 1.3–3.

Date of issuance: January 25, 2008.

Effective date: As of the date of issuance and shall be implemented within 120 days from the date of issuance.

Amendment Nos.: Unit 1—142; Unit 2—142.

Facility Operating License Nos. NPF–87 and NPF–89: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in Federal Register: April 10, 2007 (72 FR 17952). The supplemental letters dated November 30, and December 6, 2007, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register** on April 10, 2007 (72 FR 17952). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 25, 2008.

No significant hazards consideration comments received: No.

Nuclear Management Company, LLC, Docket No. 50–263, Monticello Nuclear Generating Plant, Wright County, Minnesota

Date of application for amendment: September 17, 2007.

Brief description of amendment: The amendment revised Technical Specifications Section 3.7.5 to specify the conditions and required actions associated with two control room ventilation subsystems inoperable. The revised Section 3.7.5 follows Technical Specifications Task Force (TSTF) Change Traveler TSTF–477, Revision 3, ''Add Action for Two Inoperable Control Room AC Subsystems.''

Date of issuance: January 23, 2008.

Effective date: As of the date of issuance and shall be implemented within 90 days.

Amendment No.: 154.

Facility Operating License No. DPR–22. Amendment revised the Facility Operating License and Technical Specifications.

Date of initial notice in Federal Register: November 6, 2007 (72 FR 62689).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated January 23, 2008.

No significant hazards consideration comments received: No.

Nuclear Management Company, LLC, Docket Nos. 50–282 and 50–306, Prairie Island Nuclear Generating Plant, Units 1 and 2, Goodhue County, Minnesota

Date of application for amendments: January 29, 2007, supplemented by letters dated November 19, 2007, and December 13, 2007.

Brief description of amendments: The amendments revised the Technical Specification (TS) 3.5.3 ''ECCS-Shutdown'' for Prairie Island Nuclear Generating Plant (PINGP), Units 1 and 2 to change operability requirements for the safety injection (SI) subsystem by addition of a Note to the Limiting Condition for Operation 3.5.3 ''One ECCS train shall be OPERABLE.'' The Note states ''An SI train may be considered OPERABLE when the pump is capable of being manually started from the control room.''

Date of issuance: January 28, 2008.

Effective date: As of the date of issuance and shall be implemented within 90 days.

Amendment Nos.: 183, 173.

Facility Operating License Nos. DPR–42 and DPR–60: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: March 13, 2007 (72 FR 11392).

The supplemental letters contained clarifying information and did not change the initial no significant hazards consideration determination, and did not expand the scope of the original **Federal Register** notice. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 28, 2008.

No significant hazards consideration comments received. No.

PSEG Nuclear LLC, Docket No. 50–354, Hope Creek Generating Station, Salem County, New Jersey

Date of application for amendment: April 17, 2007, as supplemented by letter dated June 29, 2007.

Brief description of amendment: The amendment establishes more effective and appropriate action, surveillance, and administrative requirements related to ensuring the habitability of the control room envelope in accordance with Nuclear Regulatory Commission approved Technical Specification Task Force (TSTF) Standard Technical Specification change traveler TSTF–448, Revision 3, ''Control Room Habitability.''

Date of issuance: January 24, 2008.

Effective date: As of the date of issuance, to be implemented within 180 days.

Amendment No.: 173.

Facility Operating License No. NPF–57: The amendment revised the Technical Specifications and the License.

Date of initial notice in Federal Register: June 5, 2007 (72 FR 31103).

The letter dated June 29, 2007, provided clarifying information that did not change the initial proposed no significant hazards consideration determination or expand the application beyond the scope of the original **Federal Register** notice.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated January 24, 2008.

No significant hazards consideration comments received: No.

PSEG Nuclear LLC, Docket Nos. 50–272 and 50–311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of application for amendments: April 15, 2007, as supplemented on December 10, 2007.

Brief description of amendments: The amendments establish more effective and appropriate action, surveillance, and administrative requirements related to ensuring the habitability of the control room envelope in accordance with Nuclear Regulatory Commission approved Technical Specification Task Force (TSTF) Standard Technical Specification change traveler TSTF–448, Revision 3, ''Control Room Habitability.''

Date of issuance: January 24, 2008.

Effective date: As of the date of issuance, to be implemented within 180 days.

Amendment Nos.: 286 and 269.

Facility Operating License Nos. DPR–70 and DPR–75: The amendments revised the Technical Specifications and the License.

Date of initial notice in Federal Register: June 5, 2007 (72 FR 31104).

The letter dated December 10, 2007, provided clarifying information that did not change the initial proposed no significant hazards consideration determination or expand the application beyond the scope of the original **Federal Register** notice.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 24, 2008.

No significant hazards consideration comments received: No

Tennessee Valley Authority, Docket No. 50–390, Watts Bar Nuclear Plant, Unit 1, Rhea County, Tennessee

Date of application for amendment: April 25, 2007, as supplemented August 22, 2007.

Brief description of amendment: The amendment revises Technical Specification Surveillance Requirements 3.5.1.4, ''Accumulators,'' and 3.5.4.3, ''Refueling Water Storage Tanks,'' to remove the note limiting the number of tritium producing burnable absorber rods (TPBARs) to no more than 240, and revises TS 4.2.1, ''Fuel Assemblies,'' to revise the maximum number of TPBARs that can be irradiated in the Watts Bar Unit 1 reactor core to 400.

Date of issuance: January 18, 2008.

Effective date: As of the date of issuance and shall be implemented within 45 days of issuance.

Amendment No.: 67.

Facility Operating License No. NPF–90: Amendment revises the Technical Specifications.

Date of initial notice in Federal Register: June 5, 2007 (72 FR 31105). The supplemental letter dated August 22, 2007, provided clarifying information that was within the scope of the initial notice and did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated January 18, 2008.

No significant hazards consideration comments received: No.

Virginia Electric and Power Company, et al., Docket Nos. 50–280 and 50–281, Surry Power Station, Unit Nos. 1 and 2, Surry County, Virginia

Date of application for amendments: February 26, 2007, as supplemented on April 5, May 31, July 13, July 20, September 25, and November 28, 2007, and January 14, 2008.

Brief description of amendments: These amendments added an operating license condition and revised the technical specifications to permit the replacement of main control room (MCR) and emergency switchgear room (ESGR) air-conditioning system (ACS) chilled water piping by using temporary 45-day and 14-day allowed outage times (AOTs) four times in a 24-month span.

Date of issuance: January 23, 2008.

Effective date: As of the date of issuance and shall be implemented within 30 days.

Amendment Nos.: 258, 257.

Renewed Facility Operating License Nos. DPR–32 and DPR–37: Amendments changed the licenses and the technical specifications.

Date of initial notice in Federal Register: March 27, 2007 (72 FR 14308).

The supplements dated April 5, May 31, July 13, July 20, September 25, and November 28, 2007, and January 14, 2008, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated January 23, 2008.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 31st day of January 2008.

For the Nuclear Regulatory Commission.

Catherine Haney,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E8–2143 Filed 2–11–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETINGS: Nuclear Regulatory Commission.

DATES: Weeks of February 11, 18, 25, March 3, 10, 17, 2008.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Matters To Be Considered

Week of February 11, 2008

Monday, February 11, 2008

1 p.m. Discussion of Security Issues (Closed—Ex. 1)

Week of February 18, 2008—Tentative

Tuesday, February 19, 2008

10:30 a.m. Meeting with the National Academies Radiation Source Use and Replacement Study Committee (Closed—Ex. 1)

Wednesday, February 20, 2008

9:30 a.m. Periodic Meeting on New Reactor Issues, Part 1 (Public Meeting) (Contact: Donna Williams, 301–415–1322)

This meeting will be webcast live at the Web address—*http://www.nrc.gov*.

1:25 p.m. Affirmation Session (Public Meeting) (Tentative)

a. Final Rule—10 CFR Part 73 ''Safeguards Information Protection Requirements'' (RIN 3150—AH57) (Tentative)

This meeting will be webcast live at the Web address—*http://www.nrc.gov*.

1:30 p.m. Periodic Meeting on New Reactor Issues, Part 2 (Public Meeting) (Contact: Donna Williams, 301–415–1322)

This meeting will be webcast live at the Web address—*http://www.nrc.gov*.

Week of February 25, 2008—Tentative

There are no meetings scheduled for the Week of February 25, 2008.

Week of March 3, 2008—Tentative

There are no meetings scheduled for the Week of March 3, 2008.

Week of March 10, 2008—Tentative

There are no meetings scheduled for the Week of March 10, 2008.

Week of March 17, 2008—Tentative

Tuesday, March 18, 2008

9:30 a.m. Briefing by Independent External Panel to Identify Vulnerabilities in the U.S. NRC's Materials Licensing Program (Public Meeting) (Contact: Aaron T. McCraw, 301–415–1277)

This meeting will be webcast live at the Web address—*http://www.nrc.gov*.

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* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—(301) 415–1292. Contact person for more information: Michelle Schroll, (301) 415–1662.

* * * * *

Additional Information

Affirmation of ''Final Rule—10 CFR Part 73 'Safeguards Information Protection Requirements' (RIN 3150–AH57)'' tentatively scheduled on February 11, 2008, at 12:55 p.m. has been tentatively rescheduled on Wednesday, February 20, 2008, at 1:25 p.m.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/about-nrc/policy-making/schedule.html*.

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify the NRC's Disability Program Coordinator, Rohn Brown, at 301–492–2279, TDD: 301–415–2100, or by e-mail at *REB3@nrc.gov*. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov*.

Dated: February 7, 2008.

R. Michelle Schroll,

Office of the Secretary.

[FR Doc. 08–657 Filed 2–8–08; 1:43 pm]

BILLING CODE 7590–01–P

POSTAL SERVICE

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Construction and Operation of a Mail Processing Facility in Aliso Viejo, CA

AGENCY: Postal Service.

ACTION: Notice.

SUMMARY: To comply with the requirements of the National Environmental Policy Act (NEPA), the Postal Service intends to prepare an Environmental Impact Statement (EIS) for the proposed construction and operation of a mail processing facility in Aliso Viejo, Orange County, California. The public is invited to participate in the project scoping process, to review and comment on the draft EIS, and to attend public meetings.

DATES: Please submit written scoping comments by March 9, 2008. This notice is the first step in the EIS process. A separate notice of availability will be issued when the draft EIS is available for public review.

To solicit public comments, a public scoping hearing will be held from 5:30 to 8:30 p.m. on February 27, 2008, at the Wood Canyon Elementary School, 23431 Knollwood Avenue, Aliso Viejo, California; (949) 448–0012.

ADDRESSES: To submit comments, request copies of the draft EIS or final EIS when available, or for more information, contact Emmy Andrews, Pacific Facilities Service Office, United States Postal Service, 395 Oyster Point Boulevard, Suite 225, South San Francisco, CA 94080–0300; (650) 615–7200.

FOR FURTHER INFORMATION CONTACT: Emmy Andrews, 650–615–7200.

SUPPLEMENTARY INFORMATION: To comply with the requirements of the National Environmental Policy Act (NEPA), the Postal Service intends to prepare an environmental impact statement (EIS) for the proposed construction and operation of a mail processing facility on a 25-acre parcel owned by the Postal Service at 50 Liberty, Aliso Viejo, Orange County, California. The EIS will be prepared in accordance with the National Environmental Policy Act (NEPA) of 1969, 42 U.S.C. 4321 *et seq.*, the Council on Environmental Quality regulations for implementing NEPA, 40

CFR parts 1500–1508, the Postal Service regulations for implementing NEPA, 32 CFR part 775, and the Postal Service Facilities Environmental Guide (Handbook RE–6, November 2004).

The proposed project will improve regional mail handling logistics, expand delivery point processing capabilities and provide more efficient mail delivery services in southern Orange County.

The proposed facility would be approximately 342,726 square feet and would contain state-of-the-art automated mail processing systems. The facility would be constructed over an 18-month period during normal daytime hours Monday through Saturday. It would include a workroom, administrative space, and employee facilities, such as restrooms and break rooms. Grading of the site would be required to achieve a uniform site elevation. In addition to the facility, the site would include two gated access roads and parking areas for tractor/trailers and employee vehicles. Other site improvements include a retaining wall along the northern edge of the site, fencing, sidewalks and curbs, outdoor lighting, a facility sign, and landscaping. Existing trees and other vegetation on the western and northern edges would remain, as would vegetation along the steeply graded eastern and southern parts of the site.

An estimated 561 full-time employees spread over three work shifts would staff the facility. Typical facility activities would include unloading unsorted mail from delivery tractor/trailers, automated mail processing, loading delivery-sequenced mail onto delivery tractor/trailers, and general administration. The facility would operate continuously, 24 hours a day, 7 days a week. It would generate an estimated 74 tractor/trailer round trips during each 24-hour period.

Alternatives that will be evaluated by the Postal Service in the EIS include the above-described proposed action and a ''No Action'' alternative. Under the ''No Action'' alternative, the mail processing facility would not be constructed. The Postal Service may consider other alternatives in the EIS, including variations on the size or functions of the proposed facility, alternate locations for the proposed facility, and other reasonable alternatives identified during the public scoping process.

The Postal Service is seeking public input on the scope of environmental issues and the range of alternatives to be addressed in the EIS. To assist with this scoping effort, copies of an environmental assessment and draft supplemental environmental assessment previously prepared for this project are available at the Aliso Viejo Library, 1 Journey (949–360–1730). Those documents are also available electronically at *http://www.alisoviejoeis.com*. All comments previously received on the environmental assessment are being considered during development of the EIS.

Neva R. Watson,

Attorney, Legislative.

[FR Doc. E8–2581 Filed 2–11–08; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 28144; 812–13427]

Pioneer Bond Fund, et al.; Notice of Application

February 5, 2008.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order pursuant to (a) section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(f) and 21(b) of the Act; (b) section 12(d)(1)(J) of the Act for an exemption from section 12(d)(1) of the Act; (c) sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(3) of the Act; and (d) section 17(d) of the Act and rule 17d–1 thereunder to permit certain joint transactions.

Summary of the Application: Applicants request an order that would permit certain registered open-end management investment companies to participate in a joint lending and borrowing facility.

Applicants: Pioneer Bond Fund, Pioneer Diversified High Income Trust, Pioneer Emerging Markets Fund, Pioneer Equity Income Fund, Pioneer Equity Opportunity Fund, Pioneer Europe Select Equity Fund, Pioneer Floating Rate Trust, Pioneer Fund, Pioneer Fundamental Growth Fund, Pioneer High Income Trust, Pioneer High Yield Fund, Pioneer Ibbotson Asset Allocation Series, Pioneer Independence Fund, Pioneer International Equity Fund, Pioneer International Value Fund, Pioneer Mid Cap Growth Fund, Pioneer Mid Cap Value Fund, Pioneer Money Market Trust, Pioneer Municipal High Income Trust, Pioneer Municipal High Income Advantage Trust, Pioneer Principal Protected Trust, Pioneer Real Estate Shares, Pioneer Research Fund, Pioneer Select Growth Fund, Pioneer Select Value Fund, Pioneer Series Trust I, Pioneer Series Trust II, Pioneer Series Trust III, Pioneer Series Trust IV, Pioneer Series Trust V, Pioneer Series Trust VI, Pioneer Series Trust VII, Pioneer Short Term Income Fund, Pioneer Small Cap Value Fund, Pioneer Strategic Income Fund, Pioneer Municipal and Equity Income Trust, Pioneer Tax Free Income Fund, Pioneer Value Fund, and Pioneer Variable Contracts Trust (each, a ''Trust'' and collectively, the ''Trusts''), and Pioneer Investment Management, Inc. (''PIM'').

Filing Dates: The application was filed on September 24, 2007, and amended on January 16, 2008.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on March 3, 2008 and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090. Applicants, 60 State Street, Boston, MA 02109–1820.

FOR FURTHER INFORMATION CONTACT: Lewis B. Reich, Senior Counsel, at (202) 551–6919, or, Nadya Roytblat, Assistant Director, at (202) 551–6821 (Office of Investment Company Regulation, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Branch, 100 F Street, NE., Washington, DC 20549–0102 (telephone (202) 551–5850).

Applicants' Representations

1. Each Trust is organized as a Delaware statutory trust or Massachusetts business trust and is either an open-end or closed-end management investment company registered under the Act.[1] Each Trust

[1] Applicants request that the order also apply to any existing or future registered management investment company that is part of the same ''group of investment companies'' as the Trusts, as defined in section 12(d)(1)(G)(ii) of the Act (included in the term ''Trusts''). All entities that currently intend to

Continued

consists of one or more series (''Funds''). PIM, a Delaware corporation and an indirect wholly-owned subsidiary of UniCredito Italiano S.p.A, is registered as an investment adviser under the Investment Advisers Act of 1940, as amended, and serves as the investment adviser and administrator of each Fund.

2. At any particular time, while some Funds are lending money to banks or other entities by entering into repurchase agreements or purchasing other short-term instruments, other Funds may need to borrow money from the same or similar banks for temporary purposes to satisfy redemption requests, to cover unanticipated cash shortfalls such as a trade ''fail'' in which cash payment for a security sold by a Fund has been delayed, or for other temporary purposes.

3. Currently, certain Funds have access to bank lines of credit for temporary borrowing purposes. If Funds borrow under those lines of credit , they pay interest on the loan at a rate that is significantly higher than the rate that is earned by other (non-borrowing) Funds on investments in repurchase agreements and other short term instruments of the same maturity as the loan. Applicants assert that this differential represents the profit earned by the lender on loans made under the lines of credit and is not attributable to any material difference in the credit quality or risk of such transactions.

4. Applicants request an order that would permit the Trusts seek to enter into master interfund lending agreements (''Interfund Lending Agreements'') with each other on behalf of the Funds that would permit each Fund to lend money directly to and borrow directly from other Funds through a credit facility for temporary purposes (''Interfund Loan''). Applicants state that the proposed credit facility would substantially reduce the Funds' potential borrowing costs and enhance the ability of the lending Funds to earn higher rates of interest on their short-term lendings. Although the proposed credit facility would substantially reduce the Funds' need to borrow from banks, the Funds would be free to establish committed lines of credit or other borrowing arrangements with unaffiliated banks. Closed-end Funds and money market Funds will not participate as borrowers in the proposed credit facility.

5. Applicants anticipate that the proposed credit facility would provide a borrowing Fund with significant savings at times when the cash position of the borrowing Fund is insufficient to meet temporary cash requirements. This situation could arise when shareholder redemptions exceed anticipated volumes and certain Funds have insufficient cash on hand to satisfy such redemptions. When the Funds liquidate portfolio securities to meet redemption requests, they often do not receive payment in settlement for up to three days (or longer for certain foreign transactions). However, redemption requests normally are effected immediately. The proposed credit facility would provide a source of immediate, short-term liquidity pending settlement of the sale of portfolio securities.

6. Applicants also propose that a Fund could use the proposed credit facility when a sale of securities ''fails'' due to circumstances beyond the Fund's control, such as a delay in the delivery of cash to the Fund's custodian or improper delivery instructions by the broker effecting the transaction. ''Sales fails'' may present a cash shortfall if the Fund has undertaken to purchase a security using the proceeds from securities sold. Alternatively, the Fund could either ''fail'' on its intended purchase due to lack of funds from the previous sale, resulting in additional cost to the Fund or sell a security on a same-day settlement basis, earning a lower return on the investment. Use of the proposed credit facility under these circumstances would enable the Fund to have access to immediate short-term liquidity without the Fund incurring custodian overdraft or other changes.

7. While bank borrowings generally could supply needed cash to cover unanticipated redemptions and sales fails, under the proposed credit facility, a borrowing Fund would pay lower interest rates than those that would be payable under short-term loans offered by banks. In addition, Funds making short-term cash loans directly to other Funds would earn interest at a rate higher than they otherwise could obtain from investing their cash in repurchase agreements or purchasing shares of a money market Fund. Thus, the proposed credit facility would benefit both borrowing and lending Funds.

8. The interest rate to be charged to the Funds on any Interfund Loan (the ''Interfund Loan Rate'') would be the average of the ''Repo Rate'' and the ''Bank Loan Rate,'' both as defined below. The Repo Rate for any day would be the highest or best (after giving effect to factors such as the credit quality of the issuer) rate available to a lending Fund from investment in overnight repurchase agreements. The Bank Loan Rate for any day would be calculated by PIM each day an Interfund Loan is made according to a formula established by each Trust's board of trustees (''Trustees'') intended to approximate the lowest interest rate at which bank short-term loans would be available to the Funds. The formula would be based upon a publicly available rate (*e.g.*, federal funds plus 50 basis points) and would vary with this rate so as to reflect changing bank loan rates. The initial formula and any subsequent modifications to the formula would be subject to the approval of each Trust's Trustees. Each Trust's Trustees would periodically review the continuing appropriateness of using the formula to determine the Bank Loan Rate, as well as the relationship between the Bank Loan Rate and current bank loan rates that would be available to the Funds. The initial formula and any subsequent modifications to it would subject to the approval of each Trust's Trustees.

9. The proposed credit facility would be administered by PIM's fund accounting department, an investment professional within PIM who serves as a portfolio manager of money market Funds and a compliance professional within PIM (collectively, the ''Credit Facility Team''). Under the proposed credit facility, the portfolio managers for each participating Fund could provide standing instructions to participate daily as a borrower or lender. The Credit Facility Team on each business day would collect data on the uninvested cash and borrowing requirements of all participating Funds. Once it determined the aggregate amount of cash available for loans and borrowing demand, the Credit Facility Team would allocate loans among borrowing Funds without any further communication from the portfolio managers of the Funds (other than the money market Fund portfolio manager acting in his or her capacity as a member of the Credit Facility Team). After the allocating cash for Interfund Loans, the Credit Facility Team would invest any remaining cash in accordance with the standing instructions of the portfolio managers or such remaining amounts will be invested directly by the portfolio managers of the Funds.

10. The Credit Facility Team would allocate borrowing demand and cash available for lending among the Funds on what the Credit Facility Team believes to be an equitable basis, subject to certain administrative procedures applicable to all Funds, such as the time of filing requests to participate, minimum loan lot sizes and the need to

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rely on the requested order have been named as applicants. Any other entity that relies on the requested order in the future will comply with the terms and conditions set forth in the application.

minimize the number of transactions and associated administrative costs. To reduce transaction costs, each loan normally would be allocated in a manner intended to minimize the number of participants necessary to complete the loan transaction. The method of allocation and related administrative procedures would be approved by each Trust's Trustees, including a majority of Trustees who are not ''interested persons'' of the Trust, as that term is defined in Section 2(a)(19) of the Act (''Independent Trustees''), to ensure that both borrowing and lending Funds participate on an equitable basis.

11. PIM, through the Credit Facility Team, would administer the proposed credit facility as part of its duties under the relevant management, advisory or administrative contract with each Fund and would receive no additional fee as compensation for its services in connection with the administration of the proposed credit facility. PIM would: (i) Monitor the Interfund Loan Rate and the other terms and conditions of the loans; (ii) limit the borrowings and loans entered into by each Fund to ensure that they comply with the Fund's investment policies and limitations; (iii) ensure equitable treatment of each Fund; and (iv) make quarterly reports to the Trustees concerning any transactions by the Funds under the proposed credit facility and the Interfund Loan Rate charged.

12. No Fund may participate in the proposed credit facility unless: (i) The Fund has obtained shareholder approval for its participation, if such approval is required by law; (ii) the Fund has fully disclosed all material information concerning the credit facility in its prospectus and/or statement of additional information; and (iii) the Fund's participation in the credit facility is consistent with its investment objectives, limitations and organizational documents.

13. In connection with the credit facility, applicants request an order under (a) section 6(c) of the Act granting relief from sections 18(f) and 21(b) of the Act; (b) section 12(d)(1)(J) of the Act granting relief from section 12(d)(1) of the Act; (c) sections 6(c) and 17(b) of the Act granting relief from sections 17(a)(1) and 17(a)(3) of the Act; and (d) under section 17(d) of the Act and rule 17d–1 under the Act to permit certain joint arrangements.

Applicants' Legal Analysis

1. Section 17(a)(3) of the Act generally prohibits any affiliated person, or affiliated person of an affiliated person, from borrowing money or other property from a registered investment company. Section 21(b) of the Act generally prohibits any registered management company from lending money or other property to any person, directly or indirectly, if that person controls or is under common control with that company. Section 2(a)(3)(C) of the Act defines an ''affiliated person'' of another person, in part, to be any person directly or indirectly controlling, controlled by, or under common control with, such other person. Section 2(a)(9) of the Act defines ''control'' as the ''power to exercise a controlling influence over the management or policies of a company,'' but excludes circumstances in which ''such power is solely the result of an official position with such company.'' Applicants state that the Funds could be deemed to be under common control by virtue of having PIM as their common investment adviser and/or by reason of having common officers and Trustees.

2. Section 6(c) of the Act provides that an exemptive order may be granted where an exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from the provisions of Section 17(a) of the Act provided that the terms of the transaction, including the consideration to be paid or received, are fair and reasonable and do not involve overreaching on the part of any person concerned, and the transaction is consistent with the policy of the investment company as recited in its registration statement and with the general purposes of the Act. Applicants assert that the proposed arrangements satisfy these standards for the reasons discussed below.

3. Applicants assert that sections 17(a)(3) and 21(b) were intended to prevent a person with strong potential adverse interests to, and some influence over the investment decisions of, a registered investment company from causing or inducing the investment company to engage in lending transactions that unfairly inure to the benefit of such person and that are detrimental to the best interests of the investment company and its shareholders. Applicants assert that the proposed credit facility transactions do not raise these concerns because: (a) PIM, through the Credit Facility Team, would administer the program as a disinterested fiduciary; (b) all Interfund Loans would consist only of uninvested cash reserves that a Fund otherwise would invest in short-term repurchase agreements or other short-term instruments; (c) the Interfund Loans would not involve a greater risk than such other investments; (d) the lending Fund would receive interest at a rate higher than it could obtain through such other investments; and (e) the borrowing Fund would pay interest at a rate lower than otherwise available to it under its bank loan agreements and avoid the quarterly commitment fees associated with committed lines of credit. Moreover, applicants believe that the other conditions in the application would effectively preclude the possibility of any Fund obtaining an undue advantage over any other Fund.

4. Section 17(a)(1) of the Act generally prohibits any affiliated person of a registered investment company, or any affiliated person of such a person, from selling securities or other property to the investment company. Section 12(d)(1) of the Act generally makes it unlawful for a registered investment company to purchasing or otherwise acquire any security issued by any other investment company except in accordance with the limitations set forth in that Section. Applicants state that the obligation of a borrowing Fund to repay an Interfund Loan may constitute a security under sections 17(a)(1) and 12(d)(1). Section 12(d)(1)(J) provides that the Commission may exempt persons or transactions from any provision of section 12(d)(1) if and to the extent that such exemption is consistent with the public interest and the protection of investors. Applicants contend that the standards under sections 6(c), 17(b), and 12(d)(1)(J) are satisfied for all the reasons set forth above in support of their request for relief from sections 17(a)(3) and 21(b) and for the reasons discussed below.

5. Applicants state that section 12(d)(1) was intended to prevent the pyramiding of investment companies in order to avoid imposing on investors additional and duplicative costs and fees attendant upon multiple layers of investment companies. Applicants assert that the proposed credit facility does not involve these abuses. Applicants note that there will be no duplicative costs or fees to the Funds or to the Funds' shareholders and that PIM will receive no additional compensation for its services in administering the credit facility. Applicants also note that the purpose of the proposed credit facility is to provide economic benefits for all of the participating Funds.

6. Section 18(f)(1) of the Act prohibits registered open-end investment companies from issuing any senior security except that a company is permitted to borrow from any bank, if immediately after the borrowing, there

is asset coverage of at least 300 per centum for all borrowings of the company. Under section 18(g) of the Act, the term ''senior security'' includes any bond, debenture, note or similar obligation or instrument constituting a security and evidencing indebtedness. Applicants request relief from section 18(f)(1) to the limited extent necessary to implement the credit facility (because the lending Funds are not banks).

7. Applicants assert that granting relief under section 6(c) of the Act is appropriate because the Funds would remain subject to the requirement of section 18(f)(1) of the Act that all borrowings of a Fund, including combined Interfund Loans and bank borrowings, have at least 300 per centum asset coverage. Based on the conditions and safeguards described in the application, applicants also assert that to allow the Funds to borrow from other Funds pursuant to the proposed credit facility is consistent with the purposes and policies of section 18(f)(1) of the Act.

8. Section 17(d) and rule 17d–1 generally prohibit any affiliated person of a registered investment company, or any affiliated person of an affiliated person, when acting as principal, from effecting any joint transaction in which the company participates unless the transaction is approved by the Commission. Rule 17d–1(b) provides that in passing upon applications filed under the rule, the Commission will consider whether the participation of a registered investment company in a joint enterprise on the basis proposed is consistent with the provisions, policies, and purposes of the Act and the extent to which the company's participation is on a basis different from or less advantageous than that of other participants.

9. Applicants assert that the purpose of section 17(d) is to avoid overreaching by and unfair advantage to investment company insiders. Applicants believe that the credit facility is consistent with the provisions, policies and purposes of the Act in that it offers both reduced borrowing costs and enhanced returns on loaned funds to all participating Funds and their shareholders. Applicants note that each Fund would have an equal opportunity to borrow and lend on equal terms consistent with its investment policies and fundamental investment limitations. Applicants therefore believe that each Fund's participation in the credit facility will be on terms that are no different from or less advantageous than that of other participating Funds.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

1. The Interfund Loan Rate will be the average of the Repo Rate and the Bank Loan Rate.

2. On each business day, the Credit Facility Team will compare the Bank Loan Rate with the Repo Rate and will make cash available for Interfund Loans only if the Interfund Loan Rate is: (i) More favorable to the lending Fund than the Repo Rate and the yield of any money market Fund in which the lending Fund could otherwise invest; and (ii) more favorable to the borrowing Fund than the Bank Loan Rate.

3. If a Fund has outstanding borrowings, any Interfund Loans to the Fund: (i) Will be at an interest rate equal to or lower than any outstanding bank loan; (ii) will be secured at least on an equal priority basis with at least an equivalent percentage of collateral to loan value as any outstanding bank loan that requires collateral; (iii) will have a maturity no longer than any outstanding bank loan (and in any event not over seven days); and (iv) will provide that, if an event of default by the Fund occurs under any agreement evidencing an outstanding bank loan to the Fund, that event of default will automatically (without need for action or notice by the lending Fund) constitute an immediate event of default under the Interfund Lending Agreement entitling the lending Fund to call the Interfund Loan (and exercise all rights with respect to any collateral) and that such call will be made if the lending bank exercises its right to call its loan under its agreement with the borrowing Fund.

4. A Fund may make an unsecured borrowing through the proposed credit facility if its outstanding borrowings from all sources immediately after the interfund borrowing, total 10% or less of its total assets, provided that if the Fund has a secured loan outstanding from any other lender, including but not limited to another Fund, the Fund's interfund borrowing will be secured on at least an equal priority basis with at least an equivalent percentage of collateral to loan value as any outstanding loan that requires collateral. If a Fund's total outstanding borrowings immediately after an interfund borrowing would be greater than 10% of its total assets, the Fund may borrow through the proposed credit facility only on a secured basis. A Fund may not borrow through the proposed credit facility or from any other source if its total outstanding borrowings immediately after such borrowing would be more than 33⅓% of its total assets.

5. Before any Fund that has outstanding interfund borrowings may, through additional borrowings, cause its outstanding borrowings from all sources to exceed 10% of its total assets, the Fund must first secure each outstanding Interfund Loan by the pledge of collateral with a market value at least equal to 102% of the outstanding principal value of the loan. If the total outstanding borrowings of a Fund with outstanding Interfund Loans exceed 10% of its total assets for any other reason (such as a decline in net asset value or because of shareholder redemptions), the Fund will within one business day thereafter: (i) Repay all its outstanding Interfund Loans; (ii) reduce its outstanding indebtedness to 10% or less of its total assets; or (iii) secure each outstanding Interfund Loan by the pledge of segregated collateral with a market value at least equal to 102% of the outstanding principal value of the loan until the Fund's total outstanding borrowings cease to exceed 10% of its total assets, at which time the collateral called for by this condition (5) shall no longer be required. Until each Interfund Loan that is outstanding at any time that a Fund's total outstanding borrowings exceed 10% is repaid or the Fund's total outstanding borrowings cease to exceed 10% of its total assets, the Fund will mark the value of the collateral to market each day and will pledge such additional collateral as is necessary to maintain the market value of the collateral that secures each outstanding Interfund Loan at least equal to 102% of the outstanding principal value of the Interfund Loan.

6. No Fund may lend to another Fund through the proposed credit facility if the loan would cause its aggregate outstanding loans through the proposed credit facility to exceed 15% of the lending Fund's current net assets at the time of the loan.

7. A Fund's Interfund Loans to any one Fund shall not exceed 5% of the lending Fund's net assets.

8. The duration of Interfund Loans will be limited to the time required to receive payment for securities sold, but in no event more than seven days. Loans effected within seven days of each other will be treated as separate loan transactions for purposes of this condition.

9. A Fund's borrowings through the proposed credit facility, as measured on the day when the most recent loan was made, will not exceed the greater of 125% of the Fund's total net cash redemptions for the preceding seven

calendar days or 102% of the Fund's sales fails for the preceding seven calendar days.

10. Each Interfund Loan may be called on one business day's notice by a lending Fund and may be repaid on any day by a borrowing Fund.

11. A Fund's participation in the proposed credit facility must be consistent with its investment objectives, and limitations and organizational documents.

12. The Credit Facility Team will calculate total Fund borrowing and lending demand through the proposed credit facility, and allocate loans on an equitable basis among the Funds, without the intervention of any portfolio manager of the Funds (other than the money market Fund portfolio manager acting in his or her capacity as a member of the Credit Facility Team). All allocations will require the approval of at least one member of the Credit Facility Team who is not the money market Fund portfolio manager. The Credit Facility Team will not solicit cash for the proposed credit facility from any Fund or prospectively publish or disseminate loan demand data to portfolio managers (except to the extent that the money market Fund portfolio manager on the Credit Facility Team has access to loan demand data). The Credit Facility Team will invest any amounts remaining after satisfaction of borrowing demand in accordance with the standing instructions of the portfolio managers or such remaining amounts will be invested directly by the portfolio managers of the Funds.

13. PIM will monitor the Interfund Loan Rate and the other terms and conditions of the Interfund Loans and will make a quarterly report to the Trustees of each Trust concerning the participation of the Funds in the proposed credit facility and the terms and other conditions of any extensions of credit under the credit facility.

14. The Trustees of each Trust, including a majority of the Independent Trustees, will: (i) Review, no less frequently than quarterly, each Fund's participation in the proposed credit facility during the preceding quarter for compliance with the conditions of any order permitting such transactions; (ii) establish the Bank Loan Rate formula used to determine the interest rate on Interfund Loans and review, no less frequently than annually, the continuing appropriateness of the Bank Loan Rate formula; and (iii) review, no less frequently than annually, the continuing appropriateness of each Fund's participation in the proposed credit facility.

15. In the event an Interfund Loan is not paid according to its terms and such default is not cured within two business days from its maturity or from the time the lending Fund makes a demand for payment under the provisions of the Interfund Lending Agreement, PIM will promptly refer such loan for arbitration to an independent arbitrator selected by the Trustees of each Fund involved in the loan who will serve as arbitrator of disputes concerning Interfund Loans.[2] The arbitrator will resolve any problem promptly, and the arbitrator's decision will be binding on both Funds. The arbitrator will submit, at least annually, a written report to the Trustees setting forth a description of the nature of any dispute and the actions taken by the Funds to resolve the dispute.

16. Each Fund will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any transaction by it under the proposed credit facility occurred, the first two years in an easily accessible place, written records of all such transactions setting forth a description of the terms of the transactions, including the amount, the maturity and the Interfund Loan Rate, the rate of interest available at the time on overnight repurchase agreements and commercial bank borrowings, the yield of any money market Fund in which the lending Fund could otherwise invest, and such other information presented to the Fund's Trustees in connection with the review required by conditions 13 and 14.

17. PIM will prepare and submit to the Trustees for review an initial report describing the operations of the proposed credit facility and the procedures to be implemented to ensure that all Funds are treated fairly. After the commencement of the proposed credit facility, PIM will report on the operations of the proposed credit facility at the Trustees' quarterly meetings.

In addition, for two years following the commencement of the credit facility, the independent public accountant for each Fund shall prepare an annual report that evaluates PIM's assertion that it has established procedures reasonably designed to achieve compliance with the terms and conditions of the order. The report will be prepared in accordance with the Statements on Standards for Attestation Engagements No. 10 and it shall be filed pursuant to Item 77Q3 of Form N–SAR as such Statements or Form may be revised, amended or superseded from time to time. In particular, the report shall address procedures designed to achieve the following objectives: (i) That the Interfund Loan Rate will be higher than the Repo Rate, and, if applicable, the yield of the money market Funds, but lower than the Bank Loan Rate; (ii) compliance with the collateral requirements as set forth in the Application; (iii) compliance with the percentage limitations on interfund borrowing and lending; (iv) allocation of interfund borrowing and lending demand in an equitable manner and in accordance with procedures established by the Board; and (v) that the Interfund Loan Rate does not exceed the interest rate on any third party borrowings of a borrowing Fund at the time of the Interfund Loan.

After the final report is filed, each Fund's independent auditors, in connection with their audit examination of the Funds, will continue to review the operation of the proposed credit facility for compliance with the conditions of the Application and their review will form the basis, in part, of the auditor's report on internal accounting controls in Form N–SAR.

18. No Fund will participate in the proposed credit facility upon receipt of requisite regulatory approval unless it has fully disclosed in its prospectus and/or statement of additional information all material facts about its intended participation.

For the Commission, by the Division of Investment Management, under delegated authority.

Florence E. Harmon,

Deputy Secretary.

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BILLING CODE 8011–01–P

[2] If the dispute involves Funds with different Trustees, the respective Trustees of each Fund will select an independent arbitrator that is satisfactory to each Fund.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57281; File No. SR–FICC–2007–08]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Proposed Rule Change as Amended by Amendment No. 1 To Resume Interbank Clearing for the GCF Repo Service

February 6, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on July 11, 2007, the Fixed Income Clearing Corporation (''FICC'') filed with the

[1] 15 U.S.C. 78s(b)(1).

Securities and Exchange Commission (''Commission'') proposed rule change SR–FICC–2007–08. On August 28, 2007, the Commission published notice of the proposed rule change to solicit comments from interested parties.[2] On January 22, 2008, FICC submitted Amendment No. 1 to the proposed rule change. The proposed rule change, as amended by Amendment No. 1, is described in Items I, II, and III below, which items have been prepared by FICC. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FICC is seeking to resume interbank clearing for the GCF Repo service.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FICC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[3]

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Background

The GCF Repo service allows FICC Government Securities Division (''GSD'') dealer members to trade GCF repos throughout the day with inter-dealer broker netting members (''brokers'') on a blind basis without requiring intraday, trade-for-trade settlement on a delivery-versus-payment (DVP) basis. Standardized, generic CUSIP numbers have been established exclusively for GCF Repo processing and are used to specify the acceptable type of underlying Fedwire book-entry eligible collateral, which includes Treasuries, Agencies, and certain mortgage-backed securities.

The GCF Repo service was developed as part of a collaborative effort among FICC's predecessor, the Government Securities Clearing Corporation (''GSCC''), its two clearing banks, The Bank of New York (''BNY'') and The Chase Manhattan Bank, now JP Morgan Chase Bank, National Association (''Chase''), and industry representatives.[4] GSCC introduced the GCF Repo service on an intraclearing bank basis in 1998.[5] Under the intrabank service, dealer members could only engage in GCF Repo transactions with other dealers that cleared at the same clearing bank.

In 1999, GSCC expanded the GCF Repo service to permit dealer members to engage in GCF Repo trading on an interclearing bank basis, which allowed dealers using different clearing banks to enter into GCF Repo transactions on a blind brokered basis.[6] Because dealer members that participated in the GCF Repo service did not, and still do not, all clear at the same clearing bank, expanding the service to be interclearing bank necessitated the establishment of a mechanism to permit after-hours movements of securities between the two clearing banks because GSCC would probably have unbalanced net GCF securities positions and unbalanced net cash positions within each clearing bank at the end of each day. (In other words, it was probable that at the end of GCF Repo processing each business day, the dealers at one clearing bank would be net funds borrowers while the dealers at the other clearing bank would be net funds lenders). To address this issue, GSCC and its clearing banks established a legal mechanism by which securities would ''move'' across the clearing banks without the use of the securities Fedwire.[7] At the end of the day after the GCF Repo net results were produced, securities were pledged using a tri-party-like mechanism, and the interbank cash component was moved through the cash Fedwire. In the morning, the pledges were unwound with the funds being returned to the net funds lenders and the securities being returned to the net funds borrowers.

However, as use of the service increased, certain payment systems risk issues from the interbank funds settlements arose. In 2003, FICC shifted the service back to intrabank status to enable it to study the risk issues presented and to devise a satisfactory solution to those issues in order that it could bring the service back to interbank status.[8]

2. Proposal

FICC is now seeking to return the GCF Repo service to interbank status. This proposed rule change would address the risk issues raised by the interbank funds movement by placing a security interest on a dealer's ''net free equity'' (''NFE'') at its clearing bank to collateralize its GCF Repo cash obligation to FICC on an intraday basis and by making changes with respect to the morning ''unwind'' period.[9] No changes are being proposed with respect to the procedures used for after-hours movement of securities, which procedures were used when the interbank service was first introduced.

Specifically, the interbank funds payment would not move during the GCF Repo morning unwind process. In lieu of making funds payments, each interbank dealer (''Interbank Pledging Member'') at the GCF net funds borrower bank would grant to FICC a security interest in its NFE-Related Collateral in an amount equal to its pro rata share of the total interbank funds debit (''Prorated Interbank Cash Amount'').[10] FICC's lien on this collateral would be pari passu to any lien created by the dealer in favor of the relevant GCF clearing bank.

FICC would in turn grant to the GCF net funds lender bank, which was due to receive funds, a security interest in the NFE-Related Collateral to support the debit in the FICC account. The debit in the FICC account (''Interbank Cash Amount Debit'') would occur because the dealers that are due to receive funds in the morning must receive those funds in return for their release of GCF collateral. The clearing banks would agree to manage the collateral value of the NFE-Related Collateral as they do today.

The debit in the FICC account at the GCF net funds lender bank would be satisfied during the end of day GCF settlement process. Specifically, that day's new activity would yield a new

[2] Securities Exchange Act Release No. 56303 (August 22, 2007), 72 FR 49339.

[3] The Commission has modified the text of the summaries prepared by FICC.

[4] BNY and Chase remain the two clearing banks approved by FICC to provide GCF Repo settlement services. In the future, other banks that FICC in its sole discretion determines meet its operational requirements may be approved to provide GCF Repo settlement services.

[5] Securities Exchange Act Release No. 40623 (October 30, 1998), 63 FR 59831 (November 5, 1998) (SR–GSCC–98–02).

[6] Securities Exchange Act Release No. 41303 (April 16, 1999), 64 FR 20346 (April 26, 1999) (SR–GSCC–99–01).

[7] Movements of cash did not present the same need because the cash Fedwire is open later than the securities Fedwire.

[8] Securities Exchange Act Release No. 48006 (June 10, 2003), 68 FR 35745 (June 16, 2003) (SR–FICC–2003–04).

[9] NFE is a methodology that clearing banks use to determine whether an account holder, such as a dealer, has sufficient collateral to enter a specific transaction. NFE allows the clearing bank to place a limit on its customer's activity by calculating a value on the customer's balances at the bank. Bank customers have the ability to monitor their NFE balance throughout the day.

[10] ''NFE-Related Collateral'' is the total amount of collateral that a dealer has at its clearing bank.

interbank funds amount to move at end of day; however, this new interbank funds amount would be netted with the amount that was due in the morning to reduce the interbank funds movement. The NFE security interest would be released when the interbank funds movement is made at end of day.

As described above, FICC would have a security interest in the dealers' NFE-Related Collateral on an intraday basis. In the unlikely event of an intraday GCF participant default, FICC would need to have the NFE-Related Collateral liquidated in order to have use of the proceeds. FICC would enter into an agreement with each of the clearing banks whereby each bank would agree to liquidate the NFE-Related Collateral both for itself as well as on behalf of FICC. FICC and each bank would agree to share pro rata in the liquidation proceeds.

Due to the nature of the various assets that may be part of a particular dealer's NFE-Related Collateral, liquidation of the NFE-Related Collateral might take longer than one day, GSD's typical collateral liquidation time frame, to be completed. Therefore, FICC would establish standby liquidity facilities or other financing arrangements with each of the clearing banks to be invoked as needed in the event of the default of an interbank pledging member.

FICC is also proposing to impose a collateral premium (''GCF Premium Charge'') on the GCF Repo portion of the Clearing Fund deposits of all GCF participants to further protect FICC in the event of an intraday default of a GCF participant. FICC would require GCF Repo participants to submit a quarterly ''snapshot'' of their holdings by asset type to enable FICC Risk Management staff to determine the appropriate Clearing Fund premium. Any GCF Repo participant that does not submit this required information by the deadlines established by FICC would be subject to a fine and an increased Clearing Fund premium.

Because the NFE-Related Collateral is held at the clearing banks and because the clearing banks monitor the activity of their dealer customers, FICC would have the right, using its sole discretion, to cease to act for a member that is a GCF Repo participant in the event that a clearing bank ceases to extend credit to such member.

The proposal results in the need for the following specific GSD rule changes.

1. The new terms referred to above (GCF Premium Charge, Interbank Cash Amount Debit, Interbank Pledging Member, NFE-Related Collateral, and Prorated Interbank Cash Amount) would be added to Rule 1 (Definitions). A new term, ''NFE-Related Account,'' which is referred to in the definition of ''NFE-Related Collateral,'' would also be added.

2. Section 3 (Collateral Allocation) of Rule 20 (Special Provisions for GCF Repo Transactions), which governs the GCF Repo collateral allocation process, would be amended to reflect the new process that would occur on the morning of the unwind (to be referred to as the morning of ''Day 2'' in the Rules).

3. Section 3 of Rule 20 would be further amended to provide for the following:

(a) the granting of the security interest in the NFE-Related Collateral to FICC by the dealers;

(b) the granting of authority for FICC to provide instructions to the clearing banks regarding the NFE-Related Collateral by the dealers;

(c) the granting of the security interest in the NFE-Related Collateral to the clearing banks by FICC; and

(d) FICC's right to enter into agreements with the clearing banks regarding the collateral management of the NFE-Related Collateral, the liquidation of the NFE-Related Collateral, and the standby liquidity facilities or other financing arrangements.

4. Rule 4 (Clearing Fund, Watch List, and Loss Allocation) would be amended to provide for the Clearing Fund premium that would be imposed on GCF Repo participants. Rule 3 (Ongoing Membership Requirements) would be amended to include the quarterly NFE reporting requirement which, if not followed timely by the members, would result in fines and Clearing Fund premium consequences.

5. Rules 21 (Restrictions on Access to Services) and 22 (Insolvency of a Member) would be amended to provide that FICC may in its sole discretion cease to act for a member in the event that the member's clearing bank has ceased to extend credit to the member.

6. The schedule of GCF time frames would be amended to reflect technical changes.

3. The Amendment

The amendment to the proposed rule change addresses the situation where FICC becomes concerned about the volume of interbank GCF Repo activity. For example, such a concern might arise if market events were to cause dealers to turn to the GCF Repo service for increased funding at levels above normal processing. In order to protect itself and its members, FICC believes it is important to have the discretion to institute risk mitigation and appropriate disincentive measures in order to bring GCF Repo levels down to a comfortable level from a risk management perspective.

Specifically, the amendment introduces the term ''GCF Repo Event,'' which would be declared by FICC if either of the following occurs: (i) the GCF interbank funds amount exceeds five times the average interbank funds amount over the previous ninety days for three consecutive days [11] or (ii) the GCF interbank funds amount exceeded fifty percent of the amount of GCF Repo collateral pledged for three consecutive days.[12] FICC would review the Repo Event triggering levels on a semi-annual basis to determine whether they remain adequate.[13] FICC would also have the right to declare a GCF Repo Event in any other circumstances where it was concerned about GCF Repo volumes and believed it was necessary to declare a Repo Event in order to protect itself and its members.[14]

The declaration of a GCF Repo Event would trigger the imposition of risk mitigation and disincentive measures. These measures would be imposed each day during the Event, and they would be imposed on each day's GCF net funds borrowers whose aggregate GCF net short position exceeded a certain threshold.[15]

Specifically, FICC would establish a ''GCF Repo Event Parameter,'' which would be a certain percentage of each dealer's average GCF Repo net short settlement amount during a one-month look-back period. FICC would establish 140 percent as the maximum percentage for the GCF Repo Event Parameter and would have the discretion to reduce this percentage during a GCF Repo Event if it believed that the maximum

[11] For example, assume that the average interbank funds amount over the previous ninety days is $11 billion. FICC would declare a GCF Repo Event if the interbank funds amount exceeded $55 billion over three consecutive days.

[12] For example, assume that on Monday the total amount of GCF Repo collateral pledged was $86.8 billion and that $11 billion was the interbank funds amount. The interbank funds amount would be 12.7 percent of the daily pledged amount. A GCF Repo Event would be declared if the overall pledged amount stayed at $86.6 billion and the interbank amount exceeded $43.3 billion for three consecutive days.

[13] Any changes to these figures would require FICC to submit a proposed rule change to the Commission.

[14] For example, FICC may determine to declare a GCF Repo Event if one of the specified events noted above occurs for less than three consecutive days.

[15] FICC would inform its members about the declaration of a GCF Repo Event by issuing an Important Notice. The Important Notice, which, would, among other things, inform members of the implementation date of the measures. FICC would also inform the Commission about the declaration of the Event. The GCF Repo Event would last until FICC notifies its members that the Event has ended.

percentage was not adequately addressing the particular event. Any GCF Repo net short settlement amount that exceeded the GCF Repo Event Parameter would be subject to a ''GCF Repo Event Clearing Fund Premium'' and a ''GCF Repo Event Carry Charge.''[16]

FICC would set 12% as the minimum percentage on which the GCF Repo Event Clearing Fund Premium would be based and 50 basis points as the minimum on which the GCF Repo Event Carry Charge would be based, and would have the discretion to increase these amounts during a GCF Repo Event if FICC believed that the minimums were not adequately addressing the particular GCF Repo Event.

FICC would retain the right to waive imposition of the GCF Repo Event Clearing Fund Premium and the GCF Repo Event Carry Charge if FICC determined, based on monitoring against the GCF Repo Event Parameters, that these measures were not necessary to protect FICC and its members.

4. Statutory Basis

FICC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act[17] and the rules and regulations thereunder applicable to FICC because it should allow GCF Repo participants to expand their use of the GCF Repo service to include GCF Repos done with dealers that clear at a different clearing bank in a manner that will support the prompt and accurate clearance and settlement of securities transactions.

B. Self-Regulatory Organization's Statement on Burden on Competition

FICC does not believe that the proposed rule change would have any impact or impose any burden on competition.

[16] For example, assume that FICC has declared a GCF Repo Event, and on the day of implementation of the protective measures, Dealer A's average net short settlement amount is $1 billion. This means that Dealer A's GCF Repo Event Parameter is $1.4 billion. On the day of implementation of the protective measures, Dealer A's net settlement amount is $1.9 billion, so the measures will be applied to $500 million (*i.e.*, $1.9 billion minus $1.4 billion). If the percentage for the GCF Repo Event Collateral Premium is 12 percent and the GCF Repo Event Carry Charge is 50 basis points, Dealer A will pay a GCF Repo Event Clearing Fund Premium of $60 million and a GCF Repo Event Carry Charge of $6,944.44 on the day of implementation. On each succeeding day that the GCF Repo Event remains in effect, FICC will reevaluate, Dealer A's net settlement position.

[17] 15 U.S.C. 78q–1.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments have not been solicited with respect to the proposed rule change, and none have been received. FICC will notify the Commission of any written comments it receives.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–FICC–2007–08 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FICC–2007–08. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 am and 3 pm. Copies of such filing also will be available for inspection and copying at the principal office of FICC and on FICC's Web site at *http://www.ficc.com/gov/gov.docs.jsp?NS-query.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FICC–2007–08 and should be submitted on or before March 4, 2008.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[18]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–2471 Filed 2–11–08; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57290; File No. SR–NASDAQ–2007–090]

Self-Regulatory Organizations; the NASDAQ Stock Market, LLC; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto to Accept Financial Statements Prepared in Accordance with International Financial Reporting Standards, as Issued by the International Accounting Standards Board, for Certain Foreign Private Issuers

February 7, 2008.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 16, 2007, the NASDAQ Stock Market, LLC (''Nasdaq'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq. Nasdaq filed Amendment No. 1 to the proposed rule

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

change on February 6, 2008. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to determine compliance with its listing standards based on financial statements prepared in accordance with International Financial Reporting Standards, as issued by the International Accounting Standards Board, for companies that are permitted to file financial statements using those standards with the Commission.

The text of the proposed rule change is below. Proposed new language is italicized; proposed deletions are in brackets.[3]

* * * * *

4320. Listing Requirements for Non-Canadian Foreign Securities and American Depositary Receipts

To qualify for listing on Nasdaq, a security of a non-Canadian foreign issuer, an American Depositary Receipt (ADR) or similar security issued in respect of a security of a foreign issuer shall satisfy the requirements of paragraphs (a), (b), and (e) of this Rule. Issuers that meet these requirements, but that are not listed on the Nasdaq Global Market, are listed on the Nasdaq Capital Market.

(a)–(d) No change.

(e) In addition to the requirements contained in paragraphs (a) and (b), the security shall satisfy the criteria set out in this subsection for listing on Nasdaq. In the case of ADRs, the underlying security will be considered when determining the ADR's qualification for initial or continued listing on Nasdaq.

(1) No change.

(2) (A)–(B) No change.

(C) An issuer's qualifications will be determined on the basis of financial statements *that are either: (i)* Prepared in accordance with U.S. generally accepted accounting principles; or *(ii)* [those accompanied by detailed schedules quantifying the differences between] *reconciled to* U.S. generally accepted accounting principles *as required by the Commission's rules* [and those of the issuer's country of domicile]; *or (iii) prepared in accordance with International Financial Reporting Standards, as issued by the International Accounting Standards Board, for companies that are permitted to file financial statements using those standards consistent with the Commission's rules.*

(D)–(E) No change.

(3)–(26) No change.

(f) No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Under current Commission rules, a foreign private issuer[4] that files financial statements with the Commission that are prepared on a basis other than U.S. generally accepted accounting principals (''U.S. GAAP'') is required to include a reconciliation to U.S. GAAP. Similarly, Nasdaq's rules require a foreign private issuer to evidence compliance with the listing standards based on financial measures prepared in accordance with U.S. GAAP or reconciled to U.S. GAAP.[5]

The Commission has recently approved a rule change to eliminate the requirement for a U.S. GAAP reconciliation for foreign private issuers that file financial statements prepared in accordance with International Financial Reporting Standards (''IFRS''), as issued by the International Accounting Standards Board (''IASB'').[6] These changes apply only to foreign private issuers that file on Form 20–F, regardless of whether the issuer complies with IFRS as issued by the IASB voluntarily or in accordance with the requirements of the issuer's home country regulator or the exchange on which its securities are listed.[7] A foreign private issuer will continue to be required to provide a reconciliation to U.S. GAAP if its financial statements include deviations from IFRS as issued by the IASB, if it does not state unreservedly and explicitly that its financial statements are in compliance with IFRS as issued by the IASB, if the auditor does not opine on compliance with IFRS as issued by the IASB, or if the auditor's report contains any qualification relating to compliance with IFRS as issued by the IASB.[8] The Commission's rules are applicable to annual financial statements for financial years ending after November 15, 2007, and to interim periods within those years, that are contained in filings made after March 4, 2008.[9]

To allow foreign private issuers to take full advantage of this development, Nasdaq proposes changes to allow such issuers to evidence compliance with Nasdaq's listing requirements on the same basis as permitted by the Commission.

Nasdaq believes that requiring companies to provide a U.S. GAAP reconciliation in order to obtain and maintain a listing on Nasdaq when they are no longer required to do so under Commission rules may result in issuers choosing not to list in the U.S. and so deny U.S. investors the ability to easily invest in such issuers. The proposed rule change would be compatible with the Commission's stated goal ''to facilitate cross-border capital formation while ensuring adequate disclosure for the protection of investors and the

[3] Changes are marked to the rule text that appears in the electronic manual of Nasdaq found at *http://nasdaq.complinet.com.*

[4] A ''foreign private issuer'' is an issuer, other than a foreign government, that is incorporated in a foreign country and either: (i) Has a majority of its voting securities held other than by United States residents, or (ii) a majority of its executives are not United States citizens/residents, a majority of its assets are located outside of the United States and its business is principally administered outside the United States. *See* Securities Exchange Act Rule 3b–4(c), 17 CFR 240.3b–4(c).

[5] Nasdaq Rule 4320(e)(2)(C).

[6] *See* Securities Exchange Act Release No. 57026 (December 21, 2007), 73 FR 986 (January 4, 2008) (the ''IFRS/IASB Adopting Release''). *See also* Securities Exchange Act Release No. 55998 (July 2, 2007), 72 FR 37962 (July 11, 2007) (the ''IFRS/IASB Proposing Release''). The Commission is also considering whether to allow U.S. issuers to satisfy their reporting requirements through the provision of financial statements prepared in accordance with IFRS instead of U.S. GAAP. *See* Securities Exchange Act Release No. 56217 (August 7, 2007), 72 FR 45600 (August 14, 2007). This proposed Nasdaq rule change would be applicable only to foreign private issuers and would not apply to domestic U.S. companies.

[7] IFRS/IASB Adopting Release at 992.

[8] *Id.* at 993. A foreign private issuer using a jurisdictional or other variation of IFRS will be able to rely on the amendments if that issuer also is able to state compliance with both IFRS as issued by the IASB and a jurisdictional variation of IFRS (and does so state), and its auditor opines that the financial statements comply with both IFRS as issued by the IASB and the jurisdictional variation, as long as the statement relating to the former is unreserved and explicit. *Id.*

[9] *Id.* at 994.

promotion of fair, orderly and efficient markets.''[10]

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of section 6 of the Act,[11] in general, and with section 6(b)(5) of the Act,[12] in particular. Section 6(b)(5) requires that an exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. Nasdaq believes that the proposed rule change is consistent with these requirements in that modifying the U.S. GAAP reconciliation requirements will ease the burden of compliance on foreign private issuers, in a manner consistent with proposed changes to the federal securities laws, and will not adversely affect investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change; or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2007–090 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2007–090. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2007–090 and should be submitted on or before March 4, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–2567 Filed 2–11–08; 8:45 am]

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[10] *See* the IFRS/IASB Proposing Release at 37965. *See also* IFRS/IASB Adopting Release at 1006 (noting that moving towards a single set of globally accepted accounting standards will have positive effects on investors).

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(5).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57278; File No. SR–FINRA–2007–010]

Self-Regulatory Organizations: Financial Industry Regulatory Authority, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of Proposed Rule Change as Modified by Amendment No. 1 To Amend an Exemption to NASD Rule 1050 and NYSE Rule Interpretation 344/02 for Certain Research Analysts Employed By a Member's Foreign Affiliate Who Contribute to the Preparation of a Member's Research Report

February 6, 2008.

I. Introduction

On September 12, 2007, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder.[2] Notice of the proposal was published for comment in the **Federal Register** on September 26, 2007.[3] The Commission received two comment letters in response to the proposed rule change.[4] On January 16, 2008, FINRA filed Amendment No. 1 to the proposed rule change to make certain modifications to the original rule filing. This order provides notice of the proposed rule change, as modified by Amendment No. 1, and approves the proposed rule change as amended on an accelerated basis.

II. Description

On September 12, 2007, FINRA filed with the Commission a proposed rule change to amend an exemption to NASD Rule 1050 and New York Stock

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 56481 (September 20, 2007), 72 FR 54700 (September 26, 2007).

[4] Securities Industry and Financial Markets Association (''SIFMA'') letter dated October 17, 2007; and WilmerHale (''WilmerHale'') letter dated October 19, 2007 on behalf of Credit Suisse Securities (USA), LLC; Goldman, Sachs & Co.; J.P. Morgan Securities Inc.; Lehman Brothers Inc.; Merrill Lynch, Pierce, Fenner & Smith Incorporated; and UBS Securities LLC.

Exchange (''NYSE'') Rule Interpretation 344/02 for certain research analysts employed by a member's foreign affiliate who contribute to the preparation of a member's research report. The Commission received two comment letters concerning the proposed rule change.[5] FINRA responded to those comments in a letter dated January 16, 2008.[6] In accordance with that response to comments, FINRA amended the proposed rule change.

NASD Rule 1050 and NYSE 344 (''Rules'') require an associated person who functions as a research analyst to register as such with FINRA and pass a qualification examination (the Series 86/87). The Rules currently provide a number of exemptions from the Series 86 examination, including certain research analysts who are employed by a member's foreign affiliate and contribute to the preparation of a member's research report. The proposed rule change would modify this exemption.

A. Current Exemption

FINRA and the NYSE consider a ''research report'' to be attributable to the member if (1) the report appears to be the product of the member or (2) a ''research analyst'' (as defined by FINRA rules) associated with a member is involved in producing the research report.[7] If either of these factors are present, the research report and any ''research analyst'' involved in its production must meet all of the applicable requirements of NASD Rules 1050 and 2711 and NYSE Rules 344 and 472.

Since the Rules require any ''research analyst'' who contributes to the preparation of a member's research report or whose name appears on such report to be registered, certain foreign analysts who contribute to the production of a member's ''globally-branded'' research or ''mixed-team'' research report could be required to meet the qualification requirements, but only if they are associated persons of the member.[8] Thus, FINRA proposed an exemption from the research analyst qualification requirements for certain research analysts employed by foreign entities in certain jurisdictions approved by FINRA and the NYSE, and subject to certain conditions. The Commission approved the proposed exemption in May 2005.[9]

Current exemptive relief for foreign analysts from the registration and qualification provisions requires compliance with other standards in foreign jurisdictions that reflect a recognition of principles that are consonant with FINRA qualification standards and the research analyst conflict of interest rules. Foreign research analysts in jurisdictions that do not have approved standards are still required to pass the Series 86 and 87 examinations if they are ''associated persons'' and participate in the preparation of a member's research report.

B. Amended Proposal

The proposed rule change would create a superseding exemption from the research analyst qualification requirements that would cover research analysts residing anywhere outside of the United States. More specifically, the requirements of NASD Rule 1050(a) and NYSE Rule 344.10 would not apply to an associated person who (1) is an employee of a non-member foreign affiliate of a member (''foreign research analyst''), (2) resides outside the United States and (3) contributes, partially or entirely, to the preparation of globally-branded or foreign affiliate research reports but does not contribute to the preparation of a member's research, including a mixed-team report, that is not globally-branded.[10] Eligibility for the exemption would further be conditioned on the member meeting certain supervisory, disclosure and recordkeeping requirements.

C. Supervisory Requirement

Members that publish or otherwise distribute globally-branded research reports partially or entirely prepared by a foreign research analyst would be required to subject such research to pre-use review and approval by a registered principal or supervisory analyst in accordance with NASD Rule 1022(a)(5) and NYSE Rule 344.11 and interpretations thereto.[11] In addition, the member would be required to ensure that such research reports comply with NASD Rule 2711 and NYSE Rule 472, as applicable.

D. Disclosure Requirement

In publishing or otherwise distributing globally-branded research reports partially or entirely prepared by a foreign research analyst, a member would be required to prominently disclose on the research report (1) each affiliate contributing to the research report, (2) the names of the foreign research analysts employed by each contributing affiliate, (3) that such research analysts are not registered/qualified as research analysts with FINRA, and (4) that such research analysts may not be associated persons of the member and therefore may not be subject to the NASD Rule 2711 and NYSE Rule 472 restrictions on communications with a subject company, public appearances and trading securities held by a research analyst account. The amended proposal, as discussed below, would require that this disclosure be presented on the front page of the research report or the front page must refer to the page on which the disclosures can be found. For electronic research reports, a member could hyperlink to the disclosure.

E. Recordkeeping Requirement

Members would be required to establish and maintain records that identify those individuals who have availed themselves of the exemption, the basis for such exemption, and evidence of compliance with the conditions of the exemption. Failure to establish and maintain such records would create an inference of a violation of NASD Rule 1050 and NYSE Rule 344. Members also would be required to establish and maintain records that evidence compliance with the applicable content, disclosure, and supervision provisions of NASD Rule 2711 and NYSE Rule 472. Members must maintain these records in accordance with the supervisory requirements of NYSE Rule 342 and NASD Rule 3010, and in addition to such requirement, the failure to establish and maintain such records would create an inference of a violation of the applicable content, disclosure, and supervision provisions of NYSE Rule 472 and NASD Rule 2711.

The proposed rule change would have no impact on the obligation of any person or broker-dealer, including a foreign broker-dealer, to comply with the applicable provisions of the federal securities laws, rules and regulations and self-regulatory organization rules. And the fact that a foreign research analyst avails herself or himself of this exemption would not be probative of whether that individual is an

[5] *Id.*

[6] The comments and responses thereto are discussed in greater detail in FINRA's Response to Comments. *See* letter from Philip Shaikun to Nancy M. Morris dated January 16, 2008.

[7] *See* NASD *Notice to Members* 04–18 and NYSE *Information Memo* 04–10. The New York Stock Exchange memo applies to its Rule 472. FINRA has incorporated both Rule 472 and the applicable interpretive guidance.

[8] FINRA *Notice to Members* 04–25 (March 2004).

[9] *See* Securities Exchange Act Release No. 51644 (May 2, 2005), 70 FR 24148 (May 6, 2005) (File No. SR–NYSE–2005–25 and SR–NASD–2005–043).

[10] When used in reference to NYSE Rule 344.10, the term ''member'' refers to both a natural person and ''member organization.''

[11] *See* NASD *Notice to Members* 04–81 and 07–04.

''associated person'' for other purposes, including whether the foreign research analyst is subject to the NASD Rule 2711 and NYSE Rule 472 restrictions on communications with a subject company, public appearances and trading securities held by a research analyst account.

As noted in the original filing, the proposed rule change would apply prospectively only and is not intended to abate any enforcement actions for failure to comply with the existing exemption. FINRA will announce the effective date of the proposed rule change in a Regulatory Notice to be published no later than 60 days following Commission approval. The effective date will be the date of publication of the *Regulatory Notice* announcing Commission approval.

III. Comment Letters

The Commission received two comment letters in response to the proposed rule change.[12] Both commenters objected to the requirement that the proposed disclosures that are a condition for the exemption for foreign research analysts appear on the front page of the research report as originally proposed by FINRA. The commenters noted that, with respect to other important disclosures required by current NASD research analyst conflict of interest rules, FINRA permits members to direct investors in a clear and prominent manner on the front page of the report to the page where the disclosures can be found. And with respect to electronic research reports, members may provide a hyperlink to the disclosures. The commenters argued that the same standard should apply with respect to the disclosures required as a condition of the proposed exemption from the research analyst registration and qualification requirements.

FINRA agreed that the disclosures required by the proposed exemption should be treated in the same manner as existing disclosures required by NASD Rule 2711 and NYSE Rule 472 and therefore amended the proposed rule change with Amendment No. 1. The amended rule text would provide that the disclosures required under the foreign analyst exemption be presented on the front page of the research report or the front page must refer to the page on which the disclosures can be found. In electronic research reports, a member could hyperlink to the disclosures. All references and disclosures would be required to be clear, comprehensive and prominent.

Both commenters also objected to the provision of the rule which would create an inference of a violation if the records required to be kept to be able to rely on the exception are not maintained by the member. The commenters believe that it would be unfair that a failure to maintain the records in support of an exemption should infer a violation of the substantive underlying rules, particularly where the failure may be accidental. FINRA responded that it believes that the inference language is necessary because much of the documentation (and potential testimonial evidence) needed by FINRA to establish a violation of the underlying rules likely resides with entities or individuals that may be beyond FINRA's jurisdiction and thus may be the only means for FINRA to enforce the conditions of the exception. FINRA further asserted that an inference does not shift the burden of proof in an enforcement case and would simply permit (not compel) a trier of fact to infer from the lack of documentation that certain facts probative of whether a violation of the underlying rule has occurred.

One commenter sought clarification on two points.[13] The commenter asked whether a globally-branded (but mixed-team) research report qualifies for the exception if all of the conditions are met. FINRA has stated that it would, but a mixed-team report that is not globally-branded would not be eligible for the exception. The commenter also asked whether a member that distributes a globally-branded research report of its foreign affiliates may treat such as third-party research in accordance with NASD Rule 2711(h)(13) and NYSE Rule 472(k)(4). FINRA responded that a globally-branded research report is considered to be a member's research report (and therefore subject to all of the provisions of NASD Rule 2711 and NYSE Rule 472) unless the member makes it clear and unambiguous to recipients that the research being distributed is wholly the product of a third party.[14] The fact that a member avails itself of the proposed exemption from the registration requirements of NASD Rule 1050 and NYSE Rule Interpretation 344/02 in connection with a particular globally-branded research report has no bearing on whether the research report is considered third-party research for purposes of NASD Rule 2711 and NYSE Rule 472. Thus, if the member is not extremely clear in identifying the report as being the product solely of its foreign affiliate, FINRA will continue to treat the research report as being that of the member, rather than third-party research.

IV. Discussion

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association.[15] In particular, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Act,[16] which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. The Commission believes that the proposed rule change will promote dissemination of globally-branded and foreign research to investors and ensure that such research has investor protection safeguards that might not otherwise be required.

The Commission also finds good cause to approve Amendment No. 1 to the proposed rule change prior to the thirtieth day after the date of publication of notice of filing of the amendment in the **Federal Register**. The proposed rule change was published in the **Federal Register** on September 26, 2007.[17] FINRA submitted Amendment No. 1 in response to comments received on the proposed rule change. The Commission believes that Amendment No. 1 simplifies the obligations of FINRA member firms but not at the expense of investor protection. Amendment No. 1 does not contain major modifications that are more restrictive than the scope of the proposed rule change as published in the **Federal Register**. The Commission believes that approving Amendment No. 1 will simplify compliance, and is consistent with the public interest and the investor protection goals of the Act. Finally, the Commission finds that it is in the public interest to approve the proposed rule change as soon as possible to expedite its implementation.

Accordingly, the Commission believes good cause exists, consistent with Sections 15A(b)(6) and 19(b) of the Act,[18] to approve Amendment No. 1 to

[12] *See* supra note 4.

[13] WilmerHale.

[14] NASD and NYSE Joint Memorandum, NASD *Notice to Members* 04–18 and NYSE *Information Memo* 04–10 (March 2004).

[15] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78o–3(b)(6).

[17] *See supra* note 3.

[18] 15 U.S.C. 78o–3(b)(6), and 78s(b).

the proposed rule change on an accelerated basis.

V. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule changes are consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–FINRA–2007–010 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR-FINRA–2007–010. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 am and 3 pm. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2007–010 and should be submitted on or before March 4, 2008.

VI. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular Section 15A of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[19] that the proposed rule change (File No. SR-FINRA–2007–010), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–2515 Filed 2–11–08; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

Release No. 34–57279; File No. SR–FINRA–2007–011]

Self-Regulatory Organizations: Financial Industry Regulatory Authority, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of Proposed Rule Change as Modified by Amendment No. 1 To Amend NASD Rule 2711 (Research Analysts and Research Reports) and NYSE Rule 472 (Communications With the Public) Regarding a Member's Disclosure and Supervisory Review Obligations When It Distributes or Makes Available Third-Party Research Reports

February 6, 2008.

I. Introduction

On September 12, 2007, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder.[2] Notice of the proposal was published for comment in the **Federal Register** on September 26, 2007.[3] The Commission received five comment letters to the proposed rule change.[4] On January 16, 2008, FINRA filed Amendment No. 1 to the proposed rule change to make certain modifications to the original rule filing. This order provides notice of the proposed rule change, as modified by Amendment No. 1, and approves the proposed rule change as amended on an accelerated basis.

II. Description

On September 12, 2007, FINRA filed with the Commission a proposed rule change to amend NASD Rule 2711 (''Research Analysts and Research Reports'') and NYSE Rule 472 (''Communications With the Public'') regarding a member's disclosure and supervisory review obligations when it distributes or makes available third-party research reports.[5] The Commission received four comment letters to the proposed rule change during the comment period.[6] FINRA responded to those comments in a letter dated January 16, 2008.[7] In accordance with that response to comments, FINRA amended the proposed rule change. The Commission then received a fifth comment letter on January 30, 2008.[8]

A. Current Rules

NASD Rule 2711(h)(13) and NYSE Rule 472(k)(4) set forth a member's disclosure and supervisory review obligations when the member distributes—*i.e.*, ''pushes out''—or makes available a research report produced by a third party. A member that distributes a third-party research report must accompany the report with certain current applicable disclosures (''third-party disclosures''), as they pertain to the member. The third-party disclosure requirements do not apply if a member makes available to its customers non-affiliate research either upon request or through a member-maintained Web site.

NASD Rule 2711(h)(13) further requires that a registered principal (or

[19] 15 U.S.C. 78s(b)(2).

[20] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 56480 (September 20, 2007), 72 FR 54698 (September 26, 2007).

[4] *See* letters to Nancy M. Morris, Secretary, Commission, from Morris N. Simkin, Esq., Katten Muchin Rosenman LLP (''Katten''), dated October 12, 2007; Stephen R. Biggar, Global Director of Equity Research, Standard & Poor's Equity Research Services (''S&P''), dated October 16, 2007; Jill Ostergaard and Christopher J. Mahon, Co-Chairs, Self Regulation and Supervisory Practices Committee, Securities Industry and Financial Markets Association (''SIFMA''), dated October 17, 2007; Stephanie R. Nicholas, WilmerHale (''WilmerHale''), dated October 19, 2007; and William D. Lyons and Arkadiy Neyman, Westminster Securities Corporation (''Westminster'') dated January 30, 2008.

[5] *See* supra note 3.

[6] Katten, S&P, SIFMA, and WilmerHale.

[7] The comments and responses thereto are discussed in greater detail in FINRA's Response to Comments. *See* letter from Philip Shaikun to Nancy M. Morris dated January 16, 2008.

[8] Westminster. FINRA had already produced a response to comments dated January 16, 2008 by the time that the Commission received this letter. Per discussion with FINRA, FINRA does not believe that this letter changes its analysis.

supervisory analyst approved pursuant to Rule 344 of the New York Stock Exchange) review and approve by signature or initial any third-party research distributed by a member. Consistent with NASD Rule 2210(d)(1)(B), the member must review such research to ensure that the applicable disclosures discussed above are complete and accurate (''disclosure review'') and the content of the research reports contains no untrue statement of material fact or is otherwise not false or misleading (''content review''). Similarly, NYSE Rule 472(k)(4) requires a supervisory analyst approved pursuant to New York Stock Exchange Rule 344 to approve by signature or initial any third-party research distributed by a member organization. Additionally, NYSE Rule 472(k)(4) requires a supervisory analyst or qualified person, designated pursuant to NYSE Rule 342(b)(1), to conduct the same disclosure and content review as NASD Rule 2711(h)(13).

FINRA has interpreted that content review requirement to mean that a member's supervisory obligation for review of third-party research extends to any untrue statement of material fact or any false or misleading information that (1) should be known from a reading of the report or (2) is known based on information otherwise possessed by the member.[9] No supervisory review is required under either rule when a member makes available non-affiliate research either upon request or through a member-maintained Web site.

B. Amended Proposal

The proposed rule change would define a ''third-party research report'' for the purposes of the rules as a research report that is produced by a person or entity other than a member. The proposal further would create the subcategory of ''independent third-party research'' and eliminate the content review requirement when a member distributes or makes available such research. The proposal, as amended, would define ''independent third-party research'' for the purposes of the rules to mean a third-party research report, in respect of which the person or entity producing the report: (1) Has no affiliation or business or contractual relationship with the distributing member or that member's affiliates that is reasonably likely to inform the content of its research reports; and (2) makes content determinations without any input from the distributing member or that member's affiliates.

The proposed rule change would create an exception from the disclosure review requirement for independent third-party research reports made available by a member either (1) upon request, (2) through a member-maintained Web site, or (3) where such report is made available by a member to a customer in connection with a solicited order in which the registered representative has informed the customer, during the course of the solicitation, of the availability of independent research on the solicited equity security and the customer requests such independent research.

The proposed rule change would require that current applicable third-party disclosures accompany any third-party research report that does not meet the definition of ''independent third-party research report,'' irrespective of whether it is distributed or made available upon request, on a member-maintained web site or in connection with a solicitation, as described above. However, the proposed rule change would amend NASD Rule 2711(h)(13) and NYSE 472(k)(4) to allow a member to direct a customer to a web address where such applicable third-party disclosures could be found. As amended, the proposal would allow members to meet the disclosure review requirement for non-independent or pushed out independent third-party research if the member establishes written supervisory polices and procedures reasonably designed to ensure the completeness and accuracy of all applicable disclosures.

FINRA will announce the effective date of the proposed rule change in a *Regulatory Notice* to be published no later than 60 days following Commission approval. The effective date will be the date of publication of the *Regulatory Notice* announcing Commission approval.

III. Comment Letters

The Commission received five comment letters to the proposed rule change.[10] The commenters generally expressed support for the proposal,[11] but requested that FINRA consider certain modifications to it. As originally proposed, this rule change would define ''independent third-party research'' to mean a research report, in respect of which the person or entity producing the report: (1) Has no affiliation or business or contractual relationship with the distributing member or that member's affiliates that is reasonably likely to inform the content of its research reports; and (2) makes both coverage and content determinations without any input from the distributing member or that member's affiliates.

One commenter[12] asserted that the prohibition on input into coverage determinations could significantly diminish a firm's ability to rely on the exception. The commenter noted that firms typically request coverage from independent research providers of particular sectors or market capitalization companies to supplement their own research or offer a second opinion of companies they cover. The commenter argued that a distributing firm's inability to control the content of a research report should suffice to establish independence and therefore the second prong of the definition is superfluous and should be eliminated.

FINRA agreed that input into coverage decisions does not necessarily compromise the independence of a third-party research report and thus amended the original proposed rule change to delete the prohibition on coverage determinations in Amendment No. 1. However, FINRA believed the remainder of the second prong of the definition (the requirement that the member have no input on the content of the report) went beyond the prohibition of a contractual or affiliate relationship prohibited by the first prong and therefore should remain. Therefore, FINRA will construe the amended second prong to mean that a distributing firm cannot have any input into the outcome of the research report. Thus, input into coverage determinations would be permissible, so long as the agreement to cover a company or sector does not carry with it an implicit understanding as to any particular conclusions or recommendations of the resultant research reports.

FINRA also received comments regarding the proposed disclosure review requirement. NASD and NYSE rules currently require a member that distributes any third-party research report to accompany the report with certain current applicable disclosures as they pertain to the member. These rules further require that a registered principal or supervisory analyst review and approve by signature or initial any third-party research distributed by a member. That review must ensure that the applicable disclosures are complete and accurate. No disclosures or review is required when the third-party

[9] *See Notice to Members* 07–04. NYSE *Information Memo* 07–11, which has been incorporated by FINRA, sets out the same standard for NYSE Rule 472(k)(4).

[10] *See* supra note 4.

[11] Westminster did not specifically express general support for the proposal and suggested changes. *See* infra.

[12] WilmerHale.

research report is made available upon request or through a member-maintained web site.

The rule change, as originally proposed, would maintain the disclosure review requirements when a member distributes independent third-party research reports, but would expand the exception to the requirement where independent third-party research is made available by a member to a customer in connection with a solicited order in which the registered representative has informed the customer, during the course of the solicitation, of the availability of such research and the customer requests it. The disclosure review requirement would still pertain where a member ''pushes out'' independent third-party research.

One commenter [13] suggested that the disclosure review requirement be more principles-based, such that firms can discharge their obligations with policies and procedures reasonably designed to ensure that the disclosures are complete and accurate. The commenter asserted that many firms have systems to populate the disclosures, where applicable, and that those disclosures are updated frequently through automated processes that derive their information from areas outside of the research department. The commenter further noted that many firms distribute thousands of third-party research reports, making it difficult or impractical to review and approve each one.

In view of the volume of third-party research reports distributed by many firms, FINRA agreed that the disclosure review requirement should be satisfied with written supervisory policies and procedures reasonably designed to ensure the completeness and accuracy of all applicable disclosures and amended its proposal accordingly in Amendment No. 1.

One commenter [14] wanted clarification that the disclosure review requirement does not apply where no disclosures are required, such as when independent third-party research is made available to a customer upon their request. FINRA agreed that no disclosure review is required under such circumstances but noted that members must have policies and procedures in place to verify that disclosures are not required in the first instance.

One commenter [15] suggested that FINRA create an exception from the disclosure requirements altogether for independent third-party research that is distributed to institutional investors. FINRA responded that it is considering providing exceptions for the application of certain of the rules under its jurisdiction for institutional investors in its efforts in developing a single consolidated NASD and NYSE rulebook.

One commenter [16] suggested that the proposal be amended to ''include language that reflects the fact that a principal or supervisory analyst assigned by a member firm to carry out the review of third party research may not be aware of all information his or her member firm employer possesses regarding a specific company, industry, etc.'' The commenter also requested that the rule text be amended to ''refer to such reviews being performed based on information that can reasonably be expected to be in the possession of the reviewer (rather than the corporate knowledge of the reviewer's entire firm).'' Per discussion with FINRA, this comment did not change their analysis.

IV. Discussion

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association.[17] In particular, the Commission finds that the proposed rule change is consistent with section 15A(b)(6) of the Act,[18] which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. The Commission believes that the proposed rule change will promote the availability of independent third party research reports, thereby resulting in more fully informed decisions by investors.

The Commission also finds good cause to approve Amendment No. 1 to the proposed rule change prior to the thirtieth day after the date of publication of notice of filing of the amendment in the **Federal Register**. The proposed rule change was published in the **Federal Register** on September 26, 2007.[19] FINRA submitted Amendment No. 1 in response to the four comments received on the proposed rule change prior to FINRA's response to those comments.[20] The Commission believes that Amendment No. 1 simplifies the obligations of FINRA member firms but not at the expense of investor protection. Amendment No. 1 does not contain major modifications that are more restrictive than the scope of the proposed rule change as published in the **Federal Register**. The Commission believes that approving Amendment No. 1 will simplify compliance and is consistent with the public interest and the investor protection goals of the Act. Finally, the Commission finds that it is in the public interest to approve the proposed rule change as soon as possible to expedite its implementation.

Accordingly, the Commission believes good cause exists, consistent with sections 15A(b)(6) and 19(b) of the Act,[21] to approve Amendment No. 1 to the proposed rule change on an accelerated basis.

V. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule changes are consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–FINRA–2007–011 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2007–011. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the

[13] SIFMA.

[14] S&P.

[15] Katten.

[16] Westminster.

[17] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[18] 15 U.S.C. 78o–3(b)(6).

[19] *See* supra note 3.

[20] As discussed above, FINRA believes that no change is necessary based on the fifth comment (Westminster) because that comment did not change their analysis.

[21] 15 U.S.C. 78o–3(b)(6), and 78s(b).

proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2007–011 and should be submitted on or before March 4, 2008.

VI. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular section 15A of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[22] that the proposed rule change (File No. SR–FINRA–2007–011), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–2518 Filed 2–11–08; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57269; File No. SR–NASDAQ–2008–008]

Self-Regulatory Organizations; The NASDAQ Stock Market, LLC; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change To Trade the Shares of Eight Funds of the ProShares Trust Based on Four International Equity Indexes Pursuant to Unlisted Trading Privileges and To Amend Certain Generic Listing Standards

February 5, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 24, 2008, The NASDAQ Stock Market, LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission ''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the Exchange. This order provides notice of the proposed rule change and approves it on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to trade, pursuant to unlisted trading privileges (''UTP''), shares (''Shares'') of eight funds of the ProShares Trust (''Trust''). Nasdaq also proposes to amend the generic listing standards contained in Nasdaq Rule 4420(m)(4).

The text of the proposed rule change is available from the Exchange's Web site (*http://nasdaq.complinet.com*), at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq proposes to trade pursuant to UTP the Shares of the eight new Funds of the Trust that are designated as Short Funds (''Short Funds'') and UltraShort Funds (''UltraShort Funds''), as described more fully below.[3] The Commission has approved the original listing and trading of the Shares on the American Stock Exchange, LLC (''Amex'').[4] Each Fund will attempt, on a daily basis, to achieve its distinct investment objective by corresponding to a specified multiple of the inverse performance of a particular equity securities index (each, an ''Underlying Index'' or ''Index'') as briefly described below.

Short Funds. Each Short Fund seeks daily investment results, before fees and expenses, that correspond to the inverse or opposite of the daily performance (-100%) of the Underlying Index. If a Short Fund is successful in meeting its objective, the net asset value (''NAV'')[5] of the corresponding Shares should increase approximately as much (on a percentage basis) as the respective Underlying Index loses when the prices of the securities in the Index decline on a given day, or should decrease approximately as much as the respective Index gains when prices in the Index rise on a given day. The Short Funds include: (1) Short MSCI Emerging Markets ProShares, (2) Short MSCI Japan ProShares, (3) Short MSCI EAFE ProShares, and (4) Short FTSE/Xinhua China 25 ProShares.

UltraShort Funds. An UltraShort Fund seeks daily investment results, before fees and expenses, that correspond to twice the inverse or opposite of the daily performance (-200%) of the Underlying Index. If an UltraShort Fund is successful in meeting its objective, the NAV of the corresponding Shares should increase approximately twice as much (on a percentage basis) as the respective Underlying Index loses when the prices of the securities in the Index decline on a given day, or should decrease approximately twice as much as the respective Underlying Index gains when such prices rise on a given day. The UltraShort Funds include: (1) UltraShort MSCI Emerging Markets ProShares, (2) UltraShort MSCI Japan ProShares, (3) UltraShort MSCI EAFE ProShares, and (4) UltraShort FTSE/Xinhua China 25 ProShares.

No Fund will invest directly in the component securities of the relevant Underlying Index; instead, each Fund will create short exposure to the corresponding Index. Each Fund will establish positions in Financial Instruments (as defined below) that

[22] 15 U.S.C. 78s(b)(2).

[23] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission has previously approved trading certain Ulta Funds, Short Funds, and UltraShort Funds of the Proshares Trust on the Exchange pursuant to UTP. *See* Securities Exchange Act Release No. 55353 (February 26, 2007), 72 FR 9802 (March 5, 2007)(SR–NASDAQ–2007–011).

[4] *See* Securities Exchange Act Release No. 56592 (October 1, 2007)(SR–Amex–2007–60)(''Amex Order''). *See also* Securities Exchange Act Release No. 56223 (August 8, 2007), 72 FR 45837 (August 15, 2007)(SR–Amex–2007–60)(''Amex Notice'').

[5] NAV per Share of each Fund is computed by dividing the value of the Fund's net assets (*i.e.,* the value of its total assets less total liabilities) by its total number of Shares outstanding. Expenses and fees are accrued daily and taken into account for purposes of determining NAV.

provide, on a daily basis, the inverse or opposite of, or twice the inverse or opposite of, the performance of the relevant Underlying Index. Normally 100% of the value of the portfolio of each Fund will be devoted to such Financial Instruments and certain money market instruments. The Financial Instruments to be held by any of the Funds may include stock index futures contracts; options on futures contracts; options on securities and indices; equity caps, collars, and floors; swap agreements; forward contracts; repurchase agreements; and reverse repurchase agreements (''Financial Instruments''). Money market instruments include certain U.S. government securities and repurchase agreements.

Availability of Information About the Shares and the Underlying Indexes

The Trust's Web site, which is and will be publicly accessible at no charge, will contain the following information for each Fund's Shares: (1) The prior business day's closing NAV, the reported closing price, and a calculation of the premium or discount of such price in relation to the closing NAV; (2) data for a period covering at least the four previous calendar quarters (or the life of a Fund, if shorter) indicating how frequently each Fund's Shares traded at a premium or discount to NAV based on the daily closing price and the closing NAV, and the magnitude of such premiums and discounts; (3) its prospectus and/or product description; and (4) other quantitative information such as daily trading volume. The prospectus and/or product description for each Fund will inform investors that the Trust's Web site has information about the premiums and discounts at which the Fund's Shares have traded.

According to the Amex Proposal, Amex will disseminate for each Fund on a daily basis by means of Consolidated Tape Association (''CTA'') and CQ High Speed Lines information with respect to an Indicative Intra-Day Value (''IIV''), recent NAV, shares outstanding, estimated cash amount, and total cash amount per Creation Unit. Amex will make available on its Web site the daily trading volume, the closing price, the NAV, and the final dividend amounts to be paid for each Fund. Amex represented in the Amex Proposal that it will obtain a representation from the Trust (for each Fund), prior to listing, that the NAV per share for each Fund will be calculated daily and made available to all market participants at the same time.[6]

Each Fund's total portfolio composition will be disclosed on the Trust's Web site (*http://www.proshares.com*) or another relevant Web site as determined by the Trust and/or Amex. According to the Amex Proposal, the Web site disclosure of portfolio holdings will be made daily and will include, as applicable, the specific types of Financial Instruments and characteristics of such instruments, cash equivalents, and the amount of cash held in the portfolio of each Fund.

This public disclosure of the portfolio composition of each Fund will coincide with the disclosure by ProShare Advisors, LLC (''Advisor'') of the ''IIV File'' and the ''PCF.''[7] Therefore, the portfolio information (including accrued expenses and dividends) to be provided on the public Web site will be the same as the information in the IIV File and PCF (when applicable) provided to authorized participants. The format of the public Web site disclosure and the IIV File and PCF (when applicable) will differ because the public Web site will list all portfolio holdings while the IIV and PCF (when applicable) will similarly provide the portfolio holdings but in a format appropriate for authorized participants, *i.e.*, the exact components of a Creation Unit.[8] Each investor will have access to the current portfolio composition of each Fund through the Trust's Web site, at *http://www.proshares.com*, and/or at the Amex's Web site at *http://www.amex.com*.

Beneficial owners of Shares (''Beneficial Owners'') will receive all of the statements, notices, and reports required under the 1940 Act and other applicable laws. They will receive, for example, annual and semi-annual Fund reports, written statements accompanying dividend payments, proxy statements, annual notifications detailing the tax status of Fund distributions, and Form 1099–DIVs. Some of these documents will be provided to Beneficial Owners by their brokers, while others will be provided by the Fund through the brokers.

The daily closing index value and the percentage change in the daily closing index value for each Underlying Index will be publicly available on various Web sites, *e.g., http://www.bloomberg.com*. Data regarding each Underlying Index are also available from the respective index provider to subscribers. Several independent data vendors also package and disseminate index data in various value-added formats (including vendors displaying both securities and index levels and vendors displaying index levels only). The value of each Underlying Index would be updated intra-day as its individual component securities change in price. These intra-day values of each Underlying Index will be disseminated at least every 60 seconds from 9:30 a.m. to 4:15 p.m. Eastern Time (''ET'') by Amex or another organization authorized by the relevant Underlying Index provider.[9]

According to the Amex Proposal, in order to provide updated information relating to each Fund for use by investors, professionals, and persons wishing to create or redeem Shares, Amex will disseminate through the facilities of the CTA: (1) Continuously from 9:30 a.m. to 4:15 p.m. ET, the market value of a Share; and (2) at least every 15 seconds from 9:30 a.m. to 4:15 p.m. ET, the IIV as calculated by Amex (the ''IIV Calculator''). Comparing these two figures helps an investor to determine whether, and to what extent, the Shares may be selling at a premium or a discount to NAV. The IIV Calculator will calculate an IIV for each Fund in the manner discussed in the Amex Proposal. The IIV is designed to provide investors with a reference value that can be used in connection with other related market information. The IIV does not necessarily reflect the precise composition of the current portfolio held by each Fund at a particular point in time. Therefore, the IIV on a per-Share basis disseminated from 9:30 a.m. to 4:15 p.m. ET should not be viewed as a real-time update of the NAV of a particular Fund, which is

[6] If Amex halts trading in the Shares of the Funds because the NAV is not being disseminated to all market participants at the same time, then the Exchange would do so as well.

[7] According to the Amex Proposal, the Trust will create a portfolio composition file (''PCF'') for each Fund, which it will transmit to the National Securities Clearing Corporation (''NSCC'') before the open of business the next business day. The information in the PCF will be available to all participants in the NSCC system. Because the NSCC's system for the receipt and dissemination to its participants of the PCF is not currently capable of processing information with respect to Financial Instruments, the Advisor has developed an ''IIV File,'' which it will use to disclose the Funds' holdings of Financial Instruments. The IIV File will contain, for each Fund, information sufficient by itself or in connection with the PCF and other available information for market participants to calculate a Fund's IIV and effectively arbitrage the Fund. The Trust or the Advisor will post the IIV File to a password-protected Web site before the opening of business on each business day, and all authorized participants and Amex will have access to a password and the Web site containing the IIV File.

[8] The composition will be used to calculate the NAV later that day.

[9] During certain periods, the relevant Underlying Index value may be not updated or static.

calculated only once a day. While the IIV that will be disseminated by Amex is expected to be close to the most recently calculated Fund NAV on a per-Share basis, it is possible that the value of the portfolio held by a Fund may diverge from the IIV during any trading day. In such case, the IIV will not precisely reflect the value of the Fund portfolio.

Trading Halts

Nasdaq will halt trading in the Shares under the conditions specified in Nasdaq Rules 4120 and 4121. The conditions for a halt include a regulatory halt by the listing market. UTP trading in the Shares of a Fund will also be governed by provisions of Nasdaq Rule 4120(b) relating to temporary interruptions in the calculation or wide dissemination of the Indicative Fund Value or the value of the Underlying Index. Additionally, Nasdaq may cease trading the Shares of a Fund if other unusual conditions or circumstances exist which, in the opinion of Nasdaq, make further dealings on Nasdaq detrimental to the maintenance of a fair and orderly market. Nasdaq will also follow any procedures with respect to trading halts as set forth in Nasdaq Rule 4120(c). Finally, Nasdaq will stop trading the Shares of a Fund if the listing market delists them.

Trading Rules

Nasdaq deems the Shares to be equity securities, thus rendering trading in the Shares subject to Nasdaq's existing rules governing the trading of equity securities. Nasdaq will allow trading in the Shares 7 a.m. until 8 p.m. ET.

Surveillance

Nasdaq believes that its surveillance procedures are adequate to address any concerns about the trading of the Shares on Nasdaq. Trading of the Shares through Nasdaq will be subject to FINRA's surveillance procedures for equity securities in general and ETFs in particular.[10] The Exchange may obtain information via the Intermarket Surveillance Group (''ISG'') from other exchanges that are members or affiliates of the ISG.[11]

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (1) The procedures for purchases and redemptions of Shares in Baskets (and that Shares are not individually redeemable); (2) Nasdaq Rule 2310, which imposes suitability obligations on Nasdaq members with respect to recommending transactions in the Shares to customers; (3) how information regarding the IFV is disseminated; (4) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (5) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Funds. The Exchange notes that investors purchasing Shares directly from a Fund (by delivery of the corresponding Cash Deposit Amount) will receive a prospectus. Members purchasing Shares from a Fund for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act.

In addition, the Information Circular will reference that the Funds are subject to various fees and expenses described in the Registration Statement. The Information Circular will also reference that the CFTC has regulatory jurisdiction over the trading of futures contracts.

The Information Circular will also disclose the trading hours of the Shares of the Funds and that the NAV for the Shares will be calculated after 4 p.m. ET each trading day. The Circular will disclose that information about the Shares of each Fund and the corresponding Index will be publicly available on the Funds' Web site.

Nasdaq Rule 4420(m)

Currently, the respective generic listing standards for such securities state, among other requirements, that the payment at maturity may or may not provide for a multiple of the positive performance of the applicable underlying Reference Asset, and in no event may payment at maturity be based on a multiple of the negative performance of the applicable underlying Reference Asset. Nasdaq seeks to amend the generic listing standards with respect to the listing and trading of an issue so that in no event may a loss or negative payment at maturity be accelerated by a multiple that exceeds twice the performance of an underlying index, indexes, or Reference Asset.[12] Nasdaq believes that the current restriction is unnecessarily limiting, given the changes in the market for these securities and the demand for differing structures. In addition, the Exchange notes that the Commission has already approved certain ETFs seeking to provide: (1) Investment results that correspond to or exceed twice (200%) the direct performance of a specified stock index, or (2) investment results that correspond to twice (−200%) the inverse or opposite of the index's performance and that such ETFs are currently listed and traded on Amex.[13]

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange. Specifically, Nasdaq believes that the proposed rule change is consistent with the Section 6(b)(5)[14] requirements that an exchange have rules designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. In addition, Nasdaq believes that the proposal is consistent with Rule 12f–5 under the Act[15] because it deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities.

[10] FINRA surveils trading on Nasdaq pursuant to a regulatory services agreement. Nasdaq is responsible for FINRA's performance under this regulatory services agreement.

[11] For a list of the current members and affiliate members of ISG, *see www.isgportal.com*.

[12] *See*, Securities Exchange Act Release No. 57150 (January 15, 2008), 73 FR 3765 (January 22, 2008) (SR–Amex–2007–130) (approving certain modifications to the initial listing standards for index-linked securities, commodity-linked securities, and currency-linked securities).

[13] *See*, *e.g.*, Securities Exchange Act Release Nos. 52553 (October 3, 2005), 70 FR 59100 (October 11, 2005) (SR–Amex–2004–62) (approving the listing and trading of shares of the xtraShares Trust); 54040 (June 23, 2006), 71 FR 37629 (June 30, 2006) (SR–Amex–2006–41) (approving the listing and trading of shares of the ProShares Trust); 55117 (January 17, 2007), 72 FR 3442 (January 25, 2007) (SR–Amex–2006–101) (approving the listing and trading of shares of the ProShares Trust based on various sector indexes); 56592 (October 1, 2007), 72 FR 57364 (October 9, 2007) (SR–Amex–2007–60) (approving the listing and trading of shares of the ProShares Trust based on various international equity indexes); and 56713 (October 29, 2007), 72 FR 61915 (November 1, 2007) (SR–Amex–2007–74) (approving the listing and trading of shares of funds of the Rydex ETF Trust).

[14] 15 U.S.C. 78f(b)(5).

[15] 17 CFR 240.12f–5.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange neither solicited nor received comments on the proposal.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2008–008 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2008–008. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2008–008 and should be submitted on or before March 4, 2008.

IV. Commission's Findings and Order Granting Accelerated Approval of the Proposed Rule Change

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[16] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[17] which requires that an exchange have rules designed, among other things, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general to protect investors and the public interest. The Commission believes that this proposal should benefit investors by increasing competition among markets that trade the Shares.

In addition, the Commission finds that the proposal is consistent with Section 12(f) of the Act,[18] which permits an exchange to trade, pursuant to UTP, a security that is listed and registered on another exchange.[19] The Commission notes that it previously approved the listing and trading of the Shares on Amex.[20] The Commission also finds that the proposal is consistent with Rule 12f–5 under the Act,[21] which provides that an exchange shall not extend UTP to a security unless the exchange has in effect a rule or rules providing for transactions in the class or type of security to which the exchange extends UTP. The Exchange has represented that it meets this requirement because it deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities.

The Commission further believes that the proposal is consistent with Section 11A(a)(1)(C)(iii) of the Act,[22] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Quotations for and last-sale information regarding the Shares are disseminated through the facilities of the CTA and the Consolidated Quotation System. In addition, Amex will calculate and disseminate the IIV per Share for each Fund through the facilities of the Consolidated Tape Association at least every 15 seconds throughout the trading hours for the Shares. The value of each Underlying Index will also be updated intra-day on a real-time basis as its individual component securities change in price and will be disseminated at least every 15 seconds throughout the trading hours for the Shares. Finally, the Trust's Web site provides various information about each Fund and its Shares.

The Commission also believes that the proposal appears reasonably designed to preclude trading of the Shares if transparency is impaired or there is unfair dissemination of the NAV. Trading in the Shares will be subject to Nasdaq Rule 4120(b), which provides that, if the listing market halts trading when the IIV or value of the underlying index is not being calculated or disseminated, the Exchange also would halt trading. Nasdaq will halt trading in the Shares of a Fund if it learns that the listing market halts trading because the NAV is not being disseminated to all market participants at the same time.

In support of this proposal, the Exchange has made the following additional representations:

1. The Exchange's surveillance procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules.

2. Prior to the commencement of trading, the Exchange would inform its members in an Information Bulletin of the special characteristics and risks associated with trading the Shares.

3. The Information Bulletin also would discuss the requirement that

[16] In approving this rule change, the Commission notes that it has considered the proposal's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78f(b)(5).

[18] 15 U.S.C. 78*l*(f).

[19] Section 12(a) of the Act, 15 U.S.C. 78*l*(a), generally prohibits a broker-dealer from trading a security on a national securities exchange unless the security is registered on that exchange pursuant to Section 12 of the Act. Section 12(f) of the Act excludes from this restriction trading in any security to which an exchange ''extends UTP.'' When an exchange extends UTP to a security, it allows its members to trade the security as if it were listed and registered on the exchange even though it is not so listed and registered.

[20] *See supra* note 4.

[21] 17 CFR 240.12f–5.

[22] 15 U.S.C. 78k–1(a)(1)(C)(iii).

members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction.

This approval order is based on the Exchange's representations.

The Commission notes that, if the Shares should be delisted by the listing exchange, the Exchange would no longer have authority to trade the Shares pursuant to this order.

The Commission also believes that the Exchange's proposal to amend Nasdaq Rule 4420(m) is consistent with the Act. The Commission notes that the proposed modifications to Nasdaq Rule 4420(m) are substantially identical to a proposal from NYSE Arca, Inc. (''NYSE Arca'') that the Commission approved and found consistent with the Act,[23] and is approving this aspect of Nasdaq's proposal on the same basis.

The Commission finds good cause for approving this proposal before the thirtieth day after the publication of notice thereof in the **Federal Register**. As noted above, the Commission previously found that the listing and trading of the Shares on Amex is consistent with the Act. In addition, the Commission notes that the proposed amendments to Nasdaq Rule 4420(m) are substantially identical to a proposed rule change submitted by NYSE Arca, which was previously approved by the Commission after an opportunity for notice and comment. The Commission presently is not aware of any regulatory issue that should cause it to revisit these findings or would preclude the trading of the Shares on the Exchange pursuant to UTP. Therefore, accelerating approval of this proposal should benefit investors by creating, without undue delay, additional competition in the market for the Shares.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[24] that the proposed rule change (SR–NASDAQ–2008–008) be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–2468 Filed 2–11–08; 8:45 am]

BILLING CODE 8011–01–P

[23] *See* Securities Exchange Act Release No. 57149 (January 15, 2008) 73 FR 3790 (January 22, 2008) (SR–NYSEARCA–2007–122).

[24] 15 U.S.C. 78s(b)(2).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57274; File No. SR-NASDAQ–2008–009]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify Fees for Members Using the Nasdaq Market Center

February 5, 2008.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 1, 2008, The NASDAQ Stock Market LLC (''Nasdaq'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared substantially by Nasdaq. Nasdaq has designated this proposal as one establishing or changing a member due, fee, or other charge imposed by Nasdaq under section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to modify pricing for Nasdaq members using the Nasdaq Market Center. Nasdaq implemented this proposed rule change on February 1, 2008. The text of the proposed rule change is available at *http://www.nasdaq.complinet.com*, the principal offices of the Exchange, and the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq is introducing changes to its order execution pricing schedule to lower fees for certain members that execute high volumes of transactions through the Nasdaq Market Center but that do not qualify for current favorable pricing because they provide lower volumes of liquidity. Specifically, any member that accesses an average of 55 million or more shares of liquidity through the Nasdaq Market Center in a month would pay a reduced fee for accessing that liquidity unless the member already qualifies for a more favorable pricing level. For shares of New York Stock Exchange (''NYSE'') listed companies, the fee will be $0.00285 per share executed in the Nasdaq Market Center,[5] and for securities listed on Nasdaq and other exchanges, the reduced fee will be $0.00265 per share executed in the Nasdaq Market Center.[6] Members qualifying for the reduced execution charge would continue to pay fees for routing to other exchanges at their current levels, which are identical to the current fees for accessing liquidity.

Second, Nasdaq is simplifying its pricing schedule by eliminating a reduced fee for orders that are designated for routing directly to the American Stock Exchange (''Amex'') without attempting to execute in the Nasdaq Market Center prior to routing. As a result, for securities listed on exchanges other than NYSE, the fee is now $0.0035 per share for all orders

[5] The fee represents a reduction from the current execution fees of $0.0029 per share paid by members with an average daily volume of (i) more than 20 million shares of liquidity provided and (ii) more than 35 million shares of liquidity accessed and/or routed; and $0.003 per share executed for members with lower volumes. Members with an average daily volume of (i) more than 35 million shares of liquidity provided and (ii) more than 55 million shares of liquidity accessed and/or routed; or with an average daily volume of (i) more than 25 million shares of liquidity provided, and (ii) more than 65 million shares of liquidity accessed and/or routed, will continue to pay a lower rate of $0.0028 per share executed.

[6] The fee represents a reduction from the current execution fees of $0.0028 per share paid by members with an average daily volume of (i) more than 20 million shares of liquidity provided and (ii) more than 35 million shares of liquidity accessed and/or routed; and $0.003 per share executed for members with lower volumes. Members with an average daily volume of (i) more than 35 million shares of liquidity provided and (ii) more than 55 million shares of liquidity accessed and/or routed; or with an average daily volume of (i) more than 25 million shares of liquidity provided, and (ii) more than 65 million shares of liquidity accessed and/or routed, will continue to pay a lower rate of $0.0026 per share executed.

designated for specialized routing, including Directed Intermarket Sweep Orders, orders that attempt to execute solely against displayed interest in Nasdaq, and orders that do not attempt to execute in Nasdaq at all.

Third, Nasdaq is reducing one of the volume levels required to qualify for a reduced fee for routing orders to NYSE. Members with an average daily volume of more than 50 million shares of liquidity (currently 60 million shares) routed to NYSE without attempting to execute in Nasdaq (other than Directed Intermarket Sweep Orders) will qualify for a fee of $0.0009 for orders that do not attempt to execute in Nasdaq (compared with the fee of $0.001 for members with lower volumes).[7]

Finally, Nasdaq is modifying its fees for routing odd lot transactions to NYSE Arca. Currently, these fees apply only to orders that are entered in Nasdaq as odd lots and then executed at NYSE Arca. The modified fees will apply to any order executed at NYSE Arca as an odd lot, regardless of how it is entered in Nasdaq. For orders that attempt to execute in Nasdaq prior to routing, the fee will be $0.004 per share executed for Nasdaq-listed securities and $0.03 for other securities; for orders that do not attempt to execute in Nasdaq, the fee will be $0.005 per share executed for Nasdaq-listed securities and $0.04 for other securities. The change is designed to allow Nasdaq to recoup charges that NYSE Arca imposes on odd lots; the higher fee for orders that do not check Nasdaq before routing is designed to further discourage the entry of odd lot orders that have no opportunity for executing prior to routing.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of section 6 of the Act,[8] in general, and with section 6(b)(4) of the Act,[9] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which Nasdaq operates or controls. The changes will result in a reduction in execution fees for members that execute high volumes of securities in Nasdaq but without also providing high volumes of liquidity, and will expand the availability of reduced routing rates for members using Nasdaq to route to the NYSE. The changes will also rationalize fees for routing orders in securities listed on exchanges other than NYSE by eliminating a discount for certain orders routed to Amex. Finally, the proposed rule change will ensure that Nasdaq fully recovers costs incurred when routing odd lots to NYSE Arca and will provide financial disincentives for members to enter orders that are likely to result in the routing of odd lots. The impact of the changes upon the net fees paid by a particular market participant will depend upon a number of variables, including the types of securities that it trades through Nasdaq, its monthly volume, the order types it uses, and the prices of its quotes and orders, but on balance the change should result in a fee decrease or unchanged fees for most members. Nasdaq notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. Accordingly, to the extent that certain routing fees are increasing, Nasdaq believes that these fees remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to those members that opt to direct orders to Nasdaq rather than competing venues.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has been designated as a fee change pursuant to section 19(b)(3)(A)(ii) of the Act[10] and Rule 19b–4(f)(2)[11] thereunder, because it establishes or changes a due, fee, or other charge imposed on members by Nasdaq. Accordingly, the proposal is effective upon filing with the Commission. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2008–009 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2008–009. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–NASDAQ–2008–009 and should be submitted on or before March 4, 2008.

[7] Members also qualify for the reduced fee if they have an average daily volume of more than 35 million shares of liquidity provided.

[8] 15 U.S.C. 78f.

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–2523 Filed 2–11–08; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57272; File No. SR–NYSE–2007–101]

Self-Regulatory Organizations; New York Stock Exchange, LLC; Order Granting Approval of Proposed Rule Change Relating to Amendments to NYSE Rule 104.21 (''Specialist Organizations—Additional Capital Requirements'')

February 5, 2008.

I. Introduction

On November 2, 2007, the New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or the ''Commission''), pursuant to section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Exchange Act'')[2] and Rule 19b–4 thereunder,[3] a proposal to amend its Rule 104.21 regarding additional capital requirements for specialist organizations. The proposed rule change was published for comment in the **Federal Register** on December 28, 2007.[4] The Commission received no comments regarding the proposal. This order approves the proposed rule changes.

II. Description of the Proposal

The proposed rule change would reduce the total base capital requirement that must be maintained as net liquid assets for all specialists from $1 billion to $250 million. NYSE believes this amount will adequately protect specialist organizations during periods of market stress. Further, each of the specialist organizations have sources of funding that can provide necessary liquidity during a period of market stress. It is no longer necessary for specialist organizations to maintain the currently required levels of liquid capital, as specialist positions and the likelihood of losses have been reduced dramatically due to changes in the structure of the market.

III. Discussion

After careful review and based on the Exchange's representations, the Commission finds that the proposed rule changes are consistent with the Act and the rules and regulations applicable to a national securities exchange.[5] In particular, the Commission finds that the proposed rule changes are consistent with section 6(b)(5)[6] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission believes it is consistent with the Act for the Exchange to amend NYSE Rule 104.21 as proposed, because the level of participation by specialist firms in trading on the Exchange has declined with the proliferation of electronic trading and the significant change in the Exchange's trading system introduced by the Hybrid Market.[7] The NYSE has noted that the increased efficiency with which others can access the Exchange's market has increased liquidity and decreased the market's reliance on the specialist to provide the contra side in a continuous auction. While the NYSE considers specialist participation to still be an important feature of its Hybrid Market, it has documented a lower participation by specialist organizations. This decreased participation means that specialists are assuming less risk.

The Commission notes that FINRA, on behalf of NYSE, will continue to assess the specialists' net liquid asset requirements in relation to the Hybrid Market and monitor their net liquid assets on a daily basis. NYSE and FINRA require notification for all withdrawals of capital, and approval for any withdrawal being made on less than six months advance notice to the Exchange.

IV. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[8] that the proposed rule change (SR–NYSE–2007–101), as amended, be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–2470 Filed 2–11–08; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57270; File No. SR–OCC–2007–20]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of a Proposed Rule Change Relating to the System for Theoretical Analysis and Numerical Simulations

February 5, 2008.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on December 14, 2007, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which items have been prepared primarily by OCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would permit the incorporation of certain forms of securities deposited as margin collateral into OCC's System for Theoretical Analysis and Numerical Simulations (''STANS'') risk management methodology.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78(a) *et seq.*

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 57000 (Dec. 20, 2007), 72 FR 73947.

[5] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78f(b)(5).

[7] *See* Release No. 34–53539 (March 22, 2006); 71 FR 16353 (March 31, 2006) File No. SR–NYSE–2004–05) (approving amendments to NYSE Rules (approving the proposed rule change to establish the NYSE Hybrid Market). The rule change created a ''Hybrid Market'' by, among other things, increasing the availability of automatic executions in its existing automatic execution facility, NYSE Direct+, and providing a means for participation in the expanded automated market by its floor members. The change altered the way NYSE's market operates by allowing more orders to be executed directly in Direct+, which in essence moves NYSE from a floor-based auction market with limited automation order interaction to a more automated market with limited floor-based auction market availability.

[8] 15 U.S.C. 78s(b)(2).

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to more accurately measure the risk in clearing members' accounts and thereby permit OCC to set margin requirements that more precisely reflect that risk. In connection with this proposed change, it is also necessary to propose additional flexibility in determining the amount of replacement collateral required when securities deposited as margin are withdrawn. In addition, because OCC believes that certain existing concentration limits and requirements regarding minimum share prices are no longer appropriately applied to securities that are underlying securities or to fund shares that track an index that is an underlying index for covered contracts, OCC is proposing to eliminate such requirements with respect to such securities.

Overview of Proposed Changes. OCC proposes to incorporate certain common stocks and ETFs (defined as ''fund shares'' in Article I of OCC's By-Laws) into the STANS margin calculation process.[3] STANS is a large-scale Monte Carlo-based risk management methodology used to measure risk associated with portfolios of cleared contracts. Currently, these forms of securities when deposited as collateral to satisfy margin requirements are priced on a nightly basis and are assigned a value equal to their end-of-day market price minus the haircut applicable to that form of collateral, an amount that varies according to asset type. While this method of valuing collateral has generally served OCC well in the past, it does not take into account the potential risk-reducing impact that the deposited collateral might have on a clearing member's portfolio. Under the proposed rule change, cleared options positions and underlying securities in the forms indicated above would be analyzed as a single portfolio using STANS, thus providing a more accurate valuation of securities deposited as collateral in relation to the other positions in the account. The proposed rule change would align risk management techniques utilized to manage market risk of options portfolios with those used to value margin deposits. There are two primary benefits expected from the rule change. First, margin requirements would be based on the risk of the combined portfolio that includes both cleared contracts and deposited collateral thereby allowing the relevant intercorrelations of cleared contracts and deposited collateral to be taken into consideration rather than treating securities deposited as collateral as having fixed values. Second, the coverage provided by a particular asset class (*e.g.*, shares of IBM common stock) would be based on the historical volatility of that particular asset rather than by taking a flat ''haircut'' rate across a much broader class of assets (*e.g.*, 30% haircut for common stock). For the period from August 16, 2007, to September 10, 2007, OCC staff computed margin requirements for all existing accounts according to this proposed approach. The result showed an average daily reduction in risk margin requirements of approximately $1.2 billion, or 5%, as compared to OCC's current approach. At the same time that average daily collateral requirements would be reduced, the STANS calculations would also measure and compensate for added risk arising where risks are positively correlated rather than offsetting.

OCC is also proposing an exception to collateral minimum price and concentration limits with respect to certain securities deposited as collateral. Currently, eligible collateral securities deposited with OCC must (1) have a market value greater than $10 per share and (2) be traded on a national securities exchange, the Nasdaq Global Market, or the Nasdaq Capital Market. Additionally, the aggregate value of margin attributed to a single security cannot exceed 10% of a clearing member's total margin requirement. These criteria were designed to limit deposits to liquid, readily marketable securities and to avoid concentrations of deposits in a single security. OCC proposes an exception to these eligibility and concentration requirements for securities that are deliverable upon exercise of a contract cleared by OCC or, in the case of ETFs, that track an index underlying cleared contracts whether or not the particular ETF is an underlying security. OCC believes that this exception would permit and encourage the use of collateral that closely hedges related options positions. The proposed exception would apply only to the approximately 2,800 exchange-listed equity securities that currently underlie listed options. Thus, OCC's existing minimum value and concentration restrictions would continue to apply to the approximate 7,200 exchange-listed equity securities that do not underlie listed options.

OCC also proposes a minor amendment to the current requirement that the aggregate value of margin attributed to a single security cannot exceed 10% of the total margin requirement in an account. The proposed change would base the calculation on the clearing member's actual margin deposits rather than the clearing member's total margin requirement in the account. Thus, the requirement as amended would limit the value given to deposits in any single security to no more than 10% of the market value of a member's aggregate margin deposits in the account. This test is very similar in purpose and effect to the current test, but OCC believes it will be much easier to administer than the current test when collateral is included in STANS.

In addition, OCC would need a different means for addressing substitutions of collateral where a security that has been valued in STANS was being replaced during the business day. STANS performs multiple portfolio revaluations during the business day using current prices of collateral and cleared contracts. While the revaluations include updated positions in cleared contracts reflecting intraday trading activity, they do not at present include updated collateral positions reflecting withdrawals and substitutions. In addition, it is operationally too intensive, given the complexity of the STANS methodology and the frequency of substitution requests, to recalculate the STANS requirement for each such collateral withdrawal/deposit. Although OCC intends ultimately to make further systems changes to address these issues in more efficient ways, OCC has developed an approach that provides the necessary protection to the clearing system by taking a conservative view of the estimated impact that a withdrawal/deposit would have on the member's requirement.

OCC proposes to treat margin collateral substitutions and withdrawals in the same manner that substitutions and withdrawals of specific and escrow deposits are treated. In the case of a margin withdrawal or deposit, OCC would incorporate an adjustment factor, based on the historical volatility of the

[2] The Commission has modified parts of these statements.

[3] For a description of STANS, refer to Securities Exchange Act Release No. 53322 (February 15, 2006) 71 FR 9403 (February 23, 2006) (File No. SR–OCC–2004–20).

security, equal to the estimated impact (within the 99% confidence interval) of the security on the projected liquidating value of the account. For example, if a clearing member deposited $300 in IBM stock and IBM is given a risk adjustment factor of 10%, the deposited stock would be given a value of $270 ($300 × [100%–10%]) in intraday excess collateral value to be used against releases to account for the potential negative risk impact of adding the stock to the portfolio. If the clearing member then released $200 of Google stock and Google is given a risk adjustment factor of 12%, the clearing member would be required to maintain $224 ($200 × [100% + 12%]) in excess collateral to account for the negative impact of removing Google from the portfolio.

Proposed Changes to OCC's Rules to Implement the Foregoing Concepts. OCC's Rule 601, ''Margin Requirements,'' currently states in paragraph (c) that margin assets may be incorporated into the Monte Carlo calculations as an alternative to valuing such assets under Rule 604, ''Form of Margin Assets.'' OCC now proposes merely to add an Interpretation to Rule 601 to indicate that OCC is implementing this alternative to the extent that it will be incorporating common stocks and ETFs into the STANS calculation of expected net liquidating value. Rule 604(b)(4), which governs the deposit of equity and debt issues to satisfy margin requirements, would be amended to provide exceptions to the per share minimum price and concentration limits and to provide that concentration limits will be measured in relation to the aggregate margin on deposit rather than to the margin requirement in an account. Rule 604(b)(4) is also proposed to be amended to reflect the fact that Nasdaq is now registered as a national securities exchange. An Interpretation is proposed to be added to Rule 608, ''Withdrawals of Margin,'' to give OCC the flexibility to adopt the interim method of dealing with collateral withdrawals and substitutions as described above. The proposed changes in Rules 609, ''Intraday Margin,'' and 706(c), ''Cross-Margining Settlement Procedures,'' would reflect minor conforming changes and nonsubstantive updates to streamline the rules and add flexibility.

OCC proposes to put all of the foregoing proposed rule changes into effect simultaneously upon appropriate notice to clearing members once systems changes needed for full implementation are in place. The published text of OCC's Rules would not be modified until that time although this rule change would be published as pending approval or approved but not yet implemented, as the case may be.

The proposed changes to OCC's Rules are consistent with the purposes and requirements of section 17A of the Act because they are designed to promote accuracy in the clearance and settlement of transactions in options and other derivatives cleared by OCC and in the risk assessments related thereto, to promote efficiency and eliminate unnecessary costs to investors by reducing risk margin requirements, and in general to protect investors and the public interest. The proposed changes accomplish this purpose by more accurately evaluating collateral deposits and encouraging the use of collateral that closely hedges options positions. The proposed changes are not inconsistent with the existing By-laws and Rules of OCC, including any proposed to be amended.

(B) Self-Regulatory Organization's Statement on Burden on Competition

OCC does not believe that the proposed rule change would impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–OCC–2007–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2007–20. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 100 F Street, NE., Washington, DC 20549, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's Web site at *http://www.optionsclearing.com.*

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–OCC–2007–20 and should be submitted on or before March 4, 2008.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[4]

Florence E. Harmon ,

Deputy Secretary.

[FR Doc. E8–2469 Filed 2–11–08; 8:45 am]

BILLING CODE 8011–01–P

[4] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 11162]

Kansas Disaster # KS–00025

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Kansas (FEMA–1741–DR), dated 02/01/2008.

Incident: Severe Winter Storms.

Incident Period: 12/06/2007 through 12/19/2007.

DATES: Effective Date: 02/01/2008.

Physical Loan Application Deadline Date: 04/02/2008.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: M. Mitravich, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 02/01/2008, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Atchison, Barber, Barton, Brown, Butler, Chase, Cherokee, Clark, Clay, Cloud, Comanche, Crawford, Dickinson, Doniphan, Edwards, Ellis, Ellsworth, Ford, Geary, Graham, Harvey, Hodgeman, Jackson, Jefferson, Jewell, Kingman, Kiowa, Labette, Leavenworth, Lincoln, Lyon, Marion, Marshall, Mcpherson, Miami, Mitchell, Morris, Nemaha, Osage, Osborne, Ottawa, Pawnee, Phillips, Pottawatomie, Pratt, Reno, Republic, Rice, Riley, Rooks, Rush, Russell, Saline, Sedgwick, Shawnee, Smith, Stafford, Wabaunsee, Washington, Woodson.

The Interest Rates are:

	Percent
Other (Including Non-Profit Organizations) With Credit Available Elsewhere	5.250
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 11162.

(Catalog of Federal Domestic Assistance Number 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–2560 Filed 2–11–08; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 6101]

60-Day Notice of Proposed Information Collection: Form–# DS–1950, Department of State Application for Employment, OMB Control #–Number 1405–0139

ACTION: Notice of request for public comments.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. The purpose of this notice is to allow 60 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995.

- *Title of Information Collection:* Department of State Application for Employment
- *OMB Control Number:* 1405–0139
- *Type of Request:* Revision of a currently approved collection
- *Originating Office:* Bureau of Human Resources, Office of Recruitment, Examination, Employment (HR/REE)
- *Form Number:* DS–1950
- *Respondents:* U.S. Citizens seeking entry into certain Department of State Foreign Service positions and individuals, sophomore through graduate level college and university students, seeking participation in the Department's student programs.
- *Estimated Number of Respondents:* 20,000
- *Estimated Number of Responses:* 20,000
- *Average Hours Per Response:* 1/2 hour
- *Total Estimated Burden:* 10,000
- *Frequency:* On occasion
- *Obligation to Respond:* Required to obtain a benefit

DATES: The Department will accept comments from the public up to 60 days from February 12, 2008.

ADDRESSES: You may submit comments by any of the following methods:

- *E-mail: studentinternprogram@state.gov.*
- *Mail (paper, disk, or CD–ROM submissions):* U.S. Department of State—SA–1, HR/REE/REC Room 518H, Attention: Marvin Moore 2401 E Street, NW., Washington DC 20522.

You must include the DS form number (if applicable), information collection title, and OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed information collection and supporting documents, to Marvin E. Moore, Bureau of Human Resources, Recruitment Division, Student Programs, U.S. Department of State, Washington, DC 20520, who may be reached on 202–261–8869 or by e-mail at *MooreME1@state.gov*.

SUPPLEMENTARY INFORMATION: We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper performance of our functions.
- Evaluate the accuracy of our estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of technology.

Abstract of proposed collection:

The DS–1950 has been the form used by individuals to apply for certain excepted jobs at the Department of State such as Foreign Service specialist and student intern positions. We wish to continue to use this form to clarify interpretation of applicant responses and how applicants become aware of our program opportunities.

Methodology:

The form will be used by applicants for excepted service jobs at the Department of State, such as Student Programs and certain Foreign Service jobs. These programs generate approximately 20,000 applications per year. Data, which is extracted from the form, is necessary to determine qualifications, and selections, in accordance with Federal policies.

Dated: December 12, 2007.

Ruben Torres,

Director, HR/EX, Department of State.

[FR Doc. E8–2570 Filed 2–11–08; 8:45 am]

BILLING CODE 4710–15–P

DEPARTMENT OF TRANSPORTATION

ITS Joint Program Office; Intelligent Transportation Systems Program Advisory Committee; Notice of Meeting

AGENCY: Research and Innovative Technology Administration, U.S. Department of Transportation.

ACTION: Notice.

This notice announces, pursuant to Section 10(A)(2) of the Federal Advisory Committee Act (FACA) (Pub. L. 72–363; 5 U.S.C. app. 2), a meeting of the Intelligent Transportation Systems (ITS) Program Advisory Committee (ITSPAC). The meeting will be held March 13, 2008, 8:30 a.m. to 4:30 p.m. The meeting will take place at the U.S. Department of Transportation (U.S. DOT), 1200 New Jersey Avenue, SE., Washington, DC, in the Oklahoma Conference Room on the lobby level of the West Building.

The ITSPAC, established under Section 5305 of Public Law 109–59, Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users, August 10, 2005, and chartered on February 24, 2006, was created to advise the Secretary of Transportation on all matters relating to the study, development and implementation of intelligent transportation systems. Through its sponsor, the ITS Joint Program Office, the ITSPAC will make recommendations to the Secretary regarding the ITS program needs, objectives, plans, approaches, contents, and progress.

The following is a summary of the meeting's tentative agenda: (1) Opening Remarks; (2) Meeting Purpose and Agenda Review; (3) Review and Discussion of Advisory Committee Input From November 2007 Meeting; (4) ITS Joint Program Office Strategic Planning Results; (5) U.S. DOT-wide Strategic Planning: Context; (6) ITS Joint Program Office Proposed Mission, Goals, and Objectives; (7) Programmatic Roles; (8) Consolidation of Views and Recommendations; and (9) Wrap-up.

Since access to the U.S. DOT building is controlled, all persons who plan to attend the meeting must notify Ms. Marcia Pincus, the Committee Management Officer, at (202) 366–9230 not later than March 11, 2008. Individuals attending the meeting must report to the 1200 New Jersey Avenue entrance of the U.S. DOT building for admission. Attendance is open to the public, but limited space is available. With the approval of Ms. Shelley Row, the Committee Designated Federal Official, members of the public may present oral statements at the meeting. Non-committee members wishing to present oral statements or obtain information should contact Ms. Pincus.

Questions about the agenda or written comments may be submitted by U.S. Mail to: U.S. Department of Transportation, Research and Innovative Technology Administration, ITS Joint Program Office, Attention: Marcia Pincus, Room E33–415, 1200 New Jersey Avenue, SE., Washington, DC 20590 or faxed to (202) 493–2027. The ITS Joint Program Office requests that written comments be submitted prior to the meeting.

Persons with a disability requiring special services, such as an interpreter for the hearing impaired, should contact Ms. Pincus at least seven calendar days prior to the meeting.

Notice of this meeting is provided in accordance with the FACA and the General Services Administration regulations (41 CFR part 102–3) covering management of Federal advisory committees.

Issued in Washington, DC, on the 6th day of February, 2008.

Shelley Row,

Director, ITS Joint Program Office.

[FR Doc. E8–2578 Filed 2–11–08; 8:45 am]

BILLING CODE 4910–HY–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on the Harrisonburg Southeast Connector Location Study in Virginia

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA.

SUMMARY: This notice announces actions taken by the FHWA that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to the Harrisonburg Southeast Connector Location Study in Rockingham County and the City of Harrisonburg, Virginia. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before August 11, 2008. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Mr. John Simkins, Environmental Protection Specialist, Federal Highway Administration, 400 North 8th Street, Room 750, Richmond, Virginia 23219; telephone: (804) 775–33242, e-mail: *John.Simkins@dot.gov.* The FHWA Virginia Divisions Office's normal business hours are 7 a.m. to 5 p.m. (eastern time). For the Virginia Department of Transportation: Mr. Nicholas Nies, Virginia Department of Transportation, 1401 East Broad Street, Richmond, Virginia 23219; telephone: (804) 786–1092; e-mail: *Nicholas.Nies@VDOT.Virginia.gov.*

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA has taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, and approvals for the following highway project in the State of Virginia: Harrisonburg Southeast Connector Location Study. The study area for the project was generally between U.S. Route 11 and U.S. route 33 in Rockingham County southeast of the City of Harrisonburg. A range of alternatives to meet the transportation needs were evaluated, and FHWA selected Candidate Build Alternative 4 and Candidate Build Alternative 1 Modified. The actions taken by FHWA, and the laws under which such actions were taken, are described in the Final Environmental Impact Statement (FEIS) for the project, approved on October 18, 2007 (FHWA–VA–EIS–06–01–F), in the FHWA Record of Decision (ROD) issued on December 21, 2007, and in other documents in the FHWA or VDOT project records. The FEIS, ROD, and other project records are available by contacting FHWA or VDOT at the addresses provided above. The FHWA FEIS and ROD can also be viewed at the project Web site at *http://www.virginiadot.org/projects/SEConnector.asp* or at VDOT's offices.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including by not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act (FAHA) [23 U.S.C. 109 and 23 U.S.C. 128].

2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303].

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and section 1536]; Marine Mammal Protection Act [16 U.S.C. 1361]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–470(ll)]; Archeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act [25 U.S.C. 3001–3013].

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act [7 U.S.C. 4201–4209].

7. *Executive Orders:* E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Population; E.O. 13007, Indian Sacred Sites.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: February 5, 2008.

John Simkins,

Environmental Protection Specialist.

[FR Doc. 08–606 Filed 2–11–08; 8:45 am]

BILLING CODE 4910–RY–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket Number NHTSA–2008–0027]

Reports, Forms, and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections. This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before April 14, 2008.

ADDRESSES: You may submit comments [identified by DOT Docket No. NHTSA–2008–0027] by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. Telephone: 1–800–647–5527.
- *Fax:* 202–493–2251.

Instructions: All submissions must include the agency name and docket number for this proposed collection of information. Note that all comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://DocketInfo.dot.gov*.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: Complete copies of each request for collection of information may be obtained at no charge from Kenneth Hardie, NHTSA 1200 New Jersey Avenue, SE., W43–458 NVS–121, Washington, DC 20590. Mr. Kenneth Hardie's telephone number is (202) 366–6987.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) how to enhance the quality, utility, and clarity of the information to be collected;

(iv) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks for public comments on the following proposed collections of information:

Title: Replaceable Light Source Dimensional Information Collection, 49 CFR Part 564

OMB Number: 2127–0563.

Type of Request: Extension of a currently approved collection.

Affected Public: Business or other for profit organizations.

Abstract: The information to be collected is in response to 49 CFR Part 564—Replaceable Light Source Information. Manufacturers of modified or original equipment light sources desiring to use newly designed replaceable light sources in headlamps are required to submit manufacturing specifications (dimensional, electrical specification, and marking/designation information) to the agency. After a short agency review to assure completeness, the information is placed in the Part 564—Replaceable Light Source Information Docket. The Part 564 Docket is a public docket available for use by any manufacturer who desired to manufacture headlamp light sources for highway motor vehicles. In Federal Motor Vehicle Safety Standard (FMVSS)

No. 108; Lamps, reflective devices and associated equipment, Part 564 submissions are referenced as being the source of information regarding the performance and interchangeability information for legal headlamp light sources, whether original equipment or replacement equipment. Thus, the submitted information about headlamp light sources becomes the basis for certification of compliance with FMVSS No. 108.

Estimated Total Annual Burden: 28.

Estimated Number of Respondents: 7.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the function of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collected; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued: February 5, 2008.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. 08–611 Filed 2–11–08; 8:45 am]

BILLING CODE 4910–59–M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA—2006—25026]

Pipeline Safety: Grant of Special Permit; Key West Pipeline Company

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT.

ACTION: Notice; grant of special permit.

SUMMARY: The Pipeline and Hazardous Materials Safety Administration (PHMSA) is granting Key West Pipeline Company (KWPC) a special permit waiving compliance from the Federal pipeline safety regulations that require a hazardous liquid pipeline operator to place a marker over the center of an exposed underwater pipeline segment that is less than 200 yards long and to bury an exposed underwater pipeline segment so that the top of the pipe is 36 inches below the underwater natural bottom for normal excavation or 18 inches for rock excavation. PHMSA finds that granting this special permit is not inconsistent with pipeline safety because the special permit analysis shows that the KWPC exposed underwater pipeline segment is in a restricted, shallow channel with surrounding water depths that would cause vessels to run aground before contacting the exposed underwater pipeline segment. Also, the United States Coast Guard (USCG) has determined that placing a marker in the channel over the center of the exposed underwater pipeline segment would pose a hazard to navigation.

FOR FURTHER INFORMATION CONTACT: Wayne Lemoi at (404) 832–1160 or by e-mail at *Wayne.Lemoi@dot.gov.*

SUPPLEMENTARY INFORMATION:

Special Permit Request

Pipeline Operator: KWPC petitioned PHMSA on January 10, 2006, for a special permit waiving compliance from the Federal pipeline safety regulations in 49 CFR 195.413(c)(2) and 195.413(c)(3) for an exposed underwater pipeline segment in the Key West, Florida area. The regulations require a hazardous liquid pipeline operator to place a marker above the center of an exposed underwater pipeline segment that is less than 200 yards long in accordance with 33 CFR part 64 and to bury an exposed underwater pipeline segment so that the top of the pipe is 36 inches below the underwater natural bottom for normal excavation or 18 inches for rock excavation. The operator must complete the burial of the pipeline within six months after discovery of the exposed pipe, or no later than November 1 of the following year if the six month period is later than November 1 of the year of discovery.

Pipeline System Affected: This special permit covers 200 feet of exposed pipe on a four mile underwater pipeline segment that runs from the Trumbo Point Naval Annex of the Key West Naval Air Station, Key West, Florida to Stock Island, Florida. The exposed segment lies in the Fleming Channel immediately adjacent to the Trumbo Point Naval Annex. Both sides of the Fleming Channel, near the exposed pipeline, are bordered by annexes of the Key West Naval Air Station. The four mile underwater pipeline segment is the western portion of the 7.1-mile, 4-inch KWPC pipeline, which transports JP5 jet fuel from KWPC's Bulk Storage and Transfer Facility on Key West to the U.S. Navy's bulk fuel storage facility on Boca Chita Key, Florida. The *special permit segment* is defined as 200 feet of the KWPC pipeline from station 0+00 to station 2+00 as shown in Figure 4 of the KWPC special permit request dated January 10, 2006.

Public Notice

On October 16, 2006, PHMSA posted notice of the KWPC request in the **Federal Register** (71 FR 60794) inviting interested persons to comment on the request. On February 8, 2007, PHMSA posted another notice in the **Federal Register** (72 FR 6042) informing the public that we have changed the name granting a waiver to a special permit. We did not receive any comments for or against this special permit request as a result of this notice. The special permit request, **Federal Register** notice and all other pertinent documents are available for review by the public in Docket Number PHMSA–2006–25026 in the Federal Docket Management System located on the internet at *www.Regulations.gov.*

Special Permit Analysis

Background: In response to the Offshore Pipelines Navigation Hazards Act, Public Law 101–599, the Federal pipeline safety regulations in 49 CFR Part 195 were amended on November 27, 1991, to require an inspection of underwater pipelines in the *Gulf of Mexico and its inlets* to be completed before November 16, 1992. Amendment 195–47 defined the *Gulf of Mexico and its inlets* to mean the waters from the mean high-water mark of the coast of the Gulf of Mexico and its inlets open to the sea (excluding rivers, tidal marshes, lakes and canals) seaward to include the territorial sea and Outer Continental Shelf (OCS) to a depth of 15 feet, as measured from the mean low water.

If during an inspection, an operator discovered a pipeline it operates was an *exposed underwater pipeline* or constituted a *hazard to navigation,* the operator was required to promptly notify the National Response Center, mark the pipeline within 7 days, and rebury the pipe 36 inches below the seabed for normal excavation or 18 inches below the seabed for rock excavation. The amendment defined *exposed underwater pipeline* to mean a pipeline where the top of the pipe is protruding above the seabed in water less than 15 feet deep, as measured from the mean low water. It defined a *hazard to navigation* to mean a pipeline where the top of the pipe is less than 12 inches below the seabed in water less than 15 feet deep, as measured from the mean low water.

To gain further information on the risks posed by underwater pipelines, the DOT's Office of Pipeline Safety (OPS) [now PHMSA] and the Department of Interior's, Minerals Management Service, requested the Marine Board,

Commission on Engineering and Technical Systems, National Research Council conduct an interdisciplinary review and assessment of the many technical, regulatory and jurisdictional issues that affect the safety of marine pipelines in the offshore waters of the United States. The National Research Council appointed the Committee on the Safety of Marine Pipelines (Committee), under the auspices of the Marine Board, to undertake the task. The Committee studied the Gulf of Mexico where about 99 percent of the marine pipeline mileage is located.

According to the Committee's 1994 report, the Committee found the marine pipeline network does not present an extraordinary threat to human life and that pipeline accidents involving deaths or injuries were rare. The Committee also found the most widespread risks posed by pipelines are oil pollution, mainly due to pipeline damage caused by vessels and their gear, and impacts from anchors, nets, trawl boards and hulls of cargo, fishing, and service vessels and mobile drilling rigs account for most of the injuries, deaths, property damage, and pollution. For example, the report notes that anchor damage alone accounted for 90 percent of the pipeline-related pollution on the OCS of the Gulf of Mexico. Moreover, the report states that very few incidents produced most of the oil pollution from pipelines. That is, the largest 11 pipeline spills caused by vessels accounted for 98 percent of the pollution from pipelines. The Committee's report concluded the risks generally can be managed with available technology and without major new regulations if enforcement of current regulations is improved.

The Committee recommended that operators inspect the depth of burial of underwater pipelines at intervals determined by analysis of the probabilities of risks. High risk areas are zones of high density of pipelines; high density of vessel traffic; shallow waters; the immediate vicinity of platforms; areas of severe erosion or shift of the sea floor and high potential for flooding; and areas affected by hurricanes or severe storms. According to the Committee report, operators should schedule surveys of pipelines using the relatively predictable behavior of sediment and shoreline erosion and after the passage of major storms.

On July 29, 2004, 49 CFR part 195 was amended (Amendment 195–82) with additional underwater inspection requirements. The new and current regulations require operators to prepare and follow a procedure to identify pipelines in the Gulf of Mexico and its inlets in waters less than 15 feet deep (as measured from mean low water) that are at risk of being *exposed underwater pipelines* or *hazards to navigation.* The regulations also require each operator to conduct periodic underwater inspections of its pipelines in the Gulf of Mexico and its inlets in waters less than 15 feet deep based on the identified risk. In lieu of reburial of the discovered underwater exposed or hazard to navigation pipeline, the regulations now allow an operator to employ engineered alternatives that meet or exceed the level of protection provided by burial.

Pipeline Marker Analysis: In its special permit petition submittals, KWPC asserted that a pipeline marker placed over the center of the KWPC exposed underwater pipeline segment in accordance with 49 CFR 195.413(c)(2) would pose a hazard to navigation in Fleming Channel. Therefore, KWPC proposed an alternate marking method to include a marker on the shorelines of both Key West and Fleming Key as well as an additional marker on the west side of the nearby road bridge linking Key West to Fleming Key.

KWPC included with its submittals to PHMSA a letter from the USCG dated September 6, 2005, which approved an alternate marking method. However, the USCG letter did not address KWPC's claim that a marker placed in the channel above the center of the exposed underwater pipeline segment would create a hazard in the channel. Therefore, PHMSA sought and received additional information on this issue. This information includes a *Special Purpose Survey* signed and certified on October 2, 2007, by a professional land surveyor registered in the state of Florida. The survey provided the coordinates of the end points and center of the exposed underwater pipeline segment. PHMSA forwarded these coordinates via e-mail to the USCG for evaluation. In a return letter to PHMSA dated November 26, 2007, the USCG stated a ''pipeline crossing sign above the center of the exposed pipeline is considered a hazard to navigation for vessels transiting Fleming Cut in that area'' and recommended that a standard ''Danger Pipeline Crossing'' sign be placed on the south side of Fleming Key Cut. KWPC's alternate marking method includes the USCG recommended sign and two other signs: One on the north side of Fleming Key Cut and one on the nearby road bridge linking Key West to Fleming Key.

Hazard to Navigation Analysis: A review of the legislative and rulemaking histories relative to inspecting underwater pipelines reveals the Offshore Pipelines Navigation Hazards Act, Public Law 101–599 and subsequent rulemaking by DOT were intended to protect the public from the hazards associated with pipeline damage caused primarily by commercial fishing vessels in the shallow waters of the northern Gulf of Mexico. Congress passed the law in response to two fatal accidents in the late 1980s in the Gulf of Mexico near the Texas and Louisiana coastlines. The DOT subsequently published regulations in response to the law and to meet its mandate to protect the public and the environment from the risks posed by underwater natural gas and hazardous liquid pipelines.

A review of the legislative and rulemaking histories also reveals there was considerable debate about what did, or did not, constitute a *hazard to navigation.* While the underwater exposed KWPC pipeline segment meets the regulatory definition of a *hazard to navigation,* there is considerable support for concluding that no actual hazard to navigation exists. This support includes the following facts provided by KWPC:

(1) The exposed underwater pipeline segment is located hundreds of miles from the primary area of concern, the northern Gulf of Mexico and its inlets.

(2) Commercial fishing vessels of the type used in the northern Gulf of Mexico do not operate in the area of the exposed underwater pipeline segment.

(3) The exposed underwater pipeline segment is in Fleming Channel, which is only used by pleasure boats seeking access to Key West Harbor from Garrison Bright and the Key West Yacht Club.

(4) Shallow waters in the Fleming Channel (11 feet) and surrounding waters limit the transit traffic in the channel to vessels with drafts less than 6.5 feet, allowing for a minimum clearance of 4.5 feet above the exposed underwater pipeline segment.

(5) Navigational charts for the Key West Harbor show the maximum clearance beneath the road bridge linking Key West with Fleming Key is 18 feet. This low bridge clearance restricts the size of vessels able to enter Fleming Channel near the exposed underwater pipeline segment.

(6) Navigational charts for Key West Harbor show the exposed underwater pipeline within a restricted, no anchorage area, under U.S. Army Corps of Engineers regulation 33 CFR 334.610, Danger Zone and Restricted Area Regulations.

(7) Both sides of Fleming Channel, near the exposed pipeline, are part of military annexes belonging to the Key West Naval Air Station. The naval air station has regulations prohibiting

anchorage within the vicinity of the exposed underwater pipeline.

A letter to KWPC of November 29, 2005, signed by the Chief, Prevention Division, Seventh Coast Guard District, USCG states:

''The pipeline is submerged in a shallow area that is transited solely by recreational vessels and surrounding waters restrict the size of vessels that can transit the Fleming Key Cut. Due to the surrounding water depths, vessels would run aground before contacting the pipeline. Furthermore, covering the pipeline with the appropriate amount of fill would reduce water depth further. Based on the above factors, I have determined the exposed section of pipeline does not pose danger to navigation that requires USCG action under existing statutory authorities.''

Special Permit Findings

PHMSA finds that granting this special permit is not inconsistent with pipeline safety and will provide a level of safety equal to or greater than reburial of the exposed underwater pipeline segment. We do so because the special permit analysis shows the following:

(1) The alternate pipeline marking method proposed by KWPC, and agreed to by the USCG, will provide for three pipeline markers in lieu of one pipeline marker and will provide adequate warning to passing boats in Fleming Channel.

(2) The alternate pipeline marking method proposed by KWPC, and agreed to by the USCG, will avoid the navigational hazard that would be created by placing a single marker above the center of the exposed underwater pipeline segment.

(3) The underwater exposed pipeline segment is in a shallow channel where it is unlikely to be struck by a commercial fishing vessel or gear from a commercial fishing vessel.

(4) The underwater exposed pipeline segment is in a shallow channel restricted area where the U.S. Navy enforces a prohibition against anchoring.

(5) The USCG states the surrounding water depths would cause vessels to run aground before contacting the underwater exposed pipeline segment.

(6) PHMSA is granting this special permit subject to conditions and limitations to ensure KWPC employs an alternate marking method to provide a level of safety equal to or greater than a marker placed above the center of the exposed underwater pipeline segment.

(7) PHMSA is granting this special permit subject to conditions and limitations to ensure KWPC employs alternative actions to provide a level of safety equal to or greater than reburial of the exposed underwater pipeline segment.

Special Permit Grant

PHMSA grants a special permit of compliance from 49 CFR 195.413(c)(2) and 95.413(c)(3) to KWPC for 200 feet of the KWPC pipeline from station 0+00 to station 2+00 as shown in Figure 4 of the KWPC special permit request dated January 10, 2006.

Special Permit Conditions

PHMSA grants this special permit with the following conditions:

(1) KWPC will place signs on the shoreline of Key West and Fleming Key, immediately adjacent to the exposed underwater pipeline segment with the following information:

WARNING Restricted Area Transit Only No Stopping or Anchoring Within 100 Yards of Shore Underwater Utility 33 CFR 334.610

(2) KWPC will place a similar sign on the west side of the road bridge linking Key West to Fleming Key.

(3) In addition to the 5-year inspections performed under KWPC's procedures for inspections of underwater segments in the Gulf of Mexico in waters less than 15 feet deep, KWPC will inspect the exposed underwater pipeline segment on an annual basis to confirm that there has been no material change in the condition of the exposed underwater pipeline segment.

(4) KWPC will notify the Director, PHMSA Southern Region within 30 days, in writing, of any

a. material change in condition of the exposed underwater pipeline segment found during any annual or 5-year inspection;

b. any reportable or non-reportable leaks or incidents on the KWPC pipeline, which impact the exposed underwater pipeline segment; and

c. mergers, acquisitions, transfer of assets or other events affecting the regulatory responsibility of the company operating the KWPC pipeline.

Special Permit Limitations

PHMSA has the sole authority to make all determinations on whether KWPC has complied with the specified conditions. Should KWPC fail to comply with any conditions of this special permit, or should PHMSA determine this special permit is no longer appropriate or that this special permit is inconsistent with pipeline safety, PHMSA may revoke this special permit and require KWPC to comply with the regulatory requirements of 49 CFR 195.413(c)(2) and 195.413(c)(3).

Authority: 49 U.S.C. 60118(c)(1) and 49 CFR 1.53.

Issued in Washington, DC on February 6, 2008.

Jeffrey D. Wiese,

Associate Administrator for Pipeline Safety.

[FR Doc. E8–2533 Filed 2–11–08; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 35095]

The Alaska Railroad Corporation—Petition for Exemption To Construct and Operate a Rail Line Extension to Port MacKenzie, AK

AGENCY: Surface Transportation Board.

ACTION: Notice of Intent to Prepare an Environmental Impact Statement; Notice of Availability of the Draft Scope of Study for the Environmental Impact Statement; Notice of Scoping Meetings; and Request for Comments on Draft Scope.

SUMMARY: The Alaska Railroad Corporation (ARRC) plans to file a petition with the Surface Transportation Board (Board) pursuant to 49 U.S.C. 10502 for authority to construct and operate approximately 30 to 45 miles of new rail line connecting the Matanuska-Susitna Borough's Port MacKenzie (or Port) in south-central Alaska to a point on the ARRC main line between Wasilla and north of Willow, Alaska. The proposed Port MacKenzie Rail Extension (or Project) would provide freight services between the Port and Interior Alaska and would support the Port's continuing development as an intermodal and bulk material resources export and import facility. The Port is owned by the Matanuska-Susitna Borough (MSB) and MSB is a co-sponsor of the Project. Because the construction and operation of this Project has the potential to result in significant environmental impacts, the Board's Section of Environmental Analysis (SEA) has determined that the preparation of an Environmental Impact Statement (EIS) is appropriate pursuant to the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*). The purpose of this Notice of Intent is to notify individuals and agencies interested in or affected by the proposed Project of the decision to prepare an EIS. SEA will hold public scoping meetings as part of the NEPA process associated with the development of the EIS. Additionally, as part of the scoping process, SEA has developed a draft Scope of Study for the

EIS for review and comment. Public meeting dates and locations, along with the draft Scope of Study, are provided herein.

Dates and Locations: The public scoping meetings will be held at the following locations:

- March 3, 2008, 5–8 p.m. at Knik Elementary School, 6350 West Hollywood, Wasilla, AK.
- March 4, 2008, 5–8 p.m. at Big Lake Elementary School, 3808 South Big Lake Road, Big Lake, AK.
- March 5, 2008, 5–8 p.m. at Willow Area Community Center, Mile 70 Parks Highway, Willow, AK.
- March 6, 2008, 5–8 p.m. at Houston Middle School, 12801 W. Hawk Lane, Houston, AK.
- March 10, 2008, 5–8 p.m., at Wasilla Multi-Use Sports Complex, 1001 S. Mack Drive, Wasilla, AK.
- March 11, 2008, 5–8 p.m. at Anchorage Senior Center, 1300 East 19th Avenue, Anchorage, AK.

The scoping meetings will be held in an informal workshop format during which interested persons may ask questions about the proposed Project and the Board's environmental review process, and advise SEA staff about potential environmental effects of the Project. No formal presentations will be made by agency representatives. SEA staff will be available to answer questions and receive comments individually.

The meeting locations comply with the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*). Persons that need special accommodations should telephone SEA's toll-free number for the Project at 1–888–257–7560.

Interested parties are invited to submit written comments on the draft Scope of Study, alternative routes for the proposed rail line, and other environmental issues and concerns by March 21, 2008, to assure full consideration during the scoping process. SEA will issue a final Scope of Study after the close of the scoping comment period.

Summary of the Board's Environmental Review Process: The NEPA process is intended to assist the Board and the public in identifying and assessing the potential environmental consequences of a proposed action before a decision on the proposed action is made. SEA is responsible for ensuring that the Board complies with NEPA and related environmental statutes. The first stage of the EIS process is scoping. Scoping is an open process for determining the scope of environmental issues to be addressed in the EIS. As part of the scoping process, SEA has developed, and has made available in this notice, a draft Scope of Study for the EIS. Concurrently, scoping meetings will be held to provide further opportunities for public involvement and input during the scoping process. In addition to the Scope of Study, interested parties are also encouraged to comment on potential routes for the proposed Project. SEA is currently considering eight alternative routes that have been identified by MSB and ARRC. At the conclusion of the scoping and comment period, SEA will issue a final Scope of Study for the EIS.

After issuing the final Scope of Study, SEA will prepare a Draft EIS for the Project. The Draft EIS will address the environmental issues and concerns identified during the scoping process. It will also contain SEA's preliminary recommendations for environmental mitigation measures. The Draft EIS will be made available upon its completion for review and comment by the public, government agencies, and other interested parties. SEA will prepare a Final EIS that considers comments on the Draft EIS. In reaching its decision in this case, the Board will take into account the Draft EIS, the Final EIS, and all environmental comments that are received.

SEA has recently invited several agencies to participate in this EIS process as cooperating agencies on the basis of their special expertise or jurisdiction by law. These agencies include: U.S. Army Corps of Engineers—Alaska District; Alaska Department of Natural Resources; and U.S. Department of Transportation, Federal Railroad Administration.

Filing Environmental Comments: Comments submitted by mail should be addressed to: David Navecky, Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001, Attention: Environmental Filing, STB Finance Docket No. 35095.

Comments may also be filed electronically on the Board's Web site, *http://www.stb.dot.gov,* by clicking on the ''E-FILING'' link.

Please refer to STB Finance Docket No. 35095 in all correspondence, including e-filings, addressed to the Board.

Comments are due by March 21, 2008.

FOR FURTHER INFORMATION CONTACT: David Navecky, Section of Environmental Analysis, Surface Transportation Board, 395 E Street, SW., Washington, DC 20423, or call SEA's toll-free number for the Project at 1–888–257–7560. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339. The Web site for the Board is *http://www.stb.dot.gov.* Project specific information on the Board's Web site may be found by placing your cursor on the ''Environmental Matters'' button, then clicking on the ''Key Cases'' button in the drop down menu.

Draft Scope of Study for the EIS

Purpose and Need

The purpose of the Project is to establish a rail link between the Port and the ARRC rail system, providing Port customers and shippers with rail transportation between the Port and Interior Alaska. The Port is a deepwater facility on the north side of Knik Arm in upper Cook Inlet, located in south-central Alaska. Presently, the only surface mode of freight transport available to the Port is trucking. The construction of a rail line would satisfy the need for an additional mode of transportation for the movement of bulk materials, intermodal containers, and other freight to and from the Port.

Proposed Action and Alternatives

The proposed rail line would extend approximately 30 to 45 miles, depending on the route selected, from the Port to ARRC's existing main line between Wasilla and north of Willow. Other major elements of the proposed Project would include a 200-foot-wide right-of-way; crossings of local roads, streams, trails, and utility corridors; sidings; and ancillary facilities. The anticipated train traffic would be two trains daily on average, with one train per day traveling in each direction. The EIS will analyze the potential impacts of alternative routes and a no-action alternative.

The reasonable and feasible alternatives that will be evaluated in the EIS are: (1) Construction and operation of the proposed rail line along several alternative alignments, (2) other route alternatives that might be identified during the scoping process, and (3) the no-action alternative.

Environmental Impact Analysis

Proposed New Construction

Analysis in the EIS will address the proposed activities associated with the construction and operation of new rail facilities and their potential environmental impacts, as appropriate.

Impact Categories

The EIS will analyze potential direct and indirect impacts for each alternative of the proposed construction and operation of new rail facilities on the human and natural environment, or in

the case of the no-action, of the lack of these activities. Impact areas addressed will include the categories of land use, recreation, biological resources, water resources including wetlands and other waters of the U.S., navigation, geology and soils, air quality, noise, energy resources, socioeconomics as they relate to physical changes in the environment, safety, grade crossing delay, cultural and historic resources, and environmental justice. Other categories of impacts may also be included as a result of comments received during the scoping process or the draft EIS. The EIS will include a discussion of each of these categories as they currently exist in the Project area and will address the potential direct and indirect impacts of each alternative on each category as described below:

1. Safety

The EIS will:

a. Describe existing road/rail grade crossing safety and analyze the potential for an increase in accidents related to the new rail operations, as appropriate.

b. Describe existing rail operations and analyze the potential for increased probability of train accidents, as appropriate.

c. Evaluate the potential for disruption and delays to the movement of emergency vehicles.

d. Propose mitigative measures to minimize or eliminate potential Project impacts to safety, as appropriate.

2. Land Use

The EIS will:

a. Evaluate potential impacts of each alternative on existing land use patterns within the Project area and identify those land uses that would be potentially impacted by new rail line construction.

b. Analyze the potential impacts associated with each alternative to land uses identified within the Project area. Such potential impacts may include incompatibility with existing land use and conversion of land to railroad use.

c. Determine if the proposed rail line is consistent with Alaska's coastal management program.

d. Propose mitigative measures to minimize or eliminate potential impacts to land use, as appropriate.

3. Recreation

The EIS will:

a. Evaluate existing conditions and the potential impacts of the alternatives, including the various new rail line construction alignments and their operation, on recreational trails and other opportunities provided in the Project area.

b. Propose mitigative measures to minimize or eliminate potential Project impacts on recreational opportunities, as appropriate.

4. Biological Resources

The EIS will:

a. Evaluate the existing biological resources within the Project area, including vegetative communities, wildlife, anadromous and other fisheries, wetlands, and Federal and state threatened or endangered species and the potential impacts to these resources resulting from each alternative.

b. Describe any wildlife sanctuaries, refuges, national or state parks, forests, or grasslands and evaluate the potential impacts to these resources resulting from each alternative.

c. Propose mitigative measures to avoid, minimize, or compensate for potential impacts to biological resources, as appropriate.

5. Water Resources

The EIS will:

a. Describe the existing surface water and groundwater resources within the Project area, including lakes, rivers, streams, stock ponds, wetlands, and floodplains and analyze the potential impacts on these resources resulting from each alternative.

b. Describe the permitting requirements for the various alternatives with regard to wetlands, stream and river crossings, water quality, floodplains, and erosion control.

c. Propose mitigative measures to avoid, minimize or compensate for potential Project impacts to water resources, as appropriate.

6. Navigation

The EIS will:

a. Identify existing navigable waterways within the Project area and analyze the potential impacts on navigability resulting from each alternative.

b. Describe the permitting requirements for the various alternatives with regards to navigation.

c. Propose mitigative measures to minimize or eliminate potential impacts to navigation, as appropriate.

7. Geology and Soils

The EIS will:

a. Describe the geology, soils and seismic conditions found within the Project area, including unique or problematic geologic formations or soils, prime farmland, and hydric soils, and analyze the potential impacts on these resources resulting from the various alternatives for construction and operation of a new rail line.

b. Evaluate potential measures employed to avoid or construct through unique or problematic geologic formations or soils.

c. Propose mitigative measures to minimize or eliminate potential Project impacts to geology and soils, as appropriate.

8. Air Quality

The EIS will:

a. Evaluate rail operation air emissions, if the alternative would affect a Class I or non-attainment or maintenance area as designated under the Clean Air Act.

b. Describe the potential air quality impact resulting from new rail line construction activities.

c. Propose mitigative measures to minimize or eliminate potential Project impacts to air quality, as appropriate.

9. Noise

The EIS will:

a. Describe the potential noise impacts during new rail line construction.

b. Describe the potential noise impacts of new rail line operation.

c. Propose mitigative measures to minimize or eliminate potential Project impacts to sensitive noise receptors, as appropriate.

10. Energy Resources

The EIS will:

a. Describe and evaluate the potential impact of the new rail line on the distribution of energy resources in the Project area for each alternative, including petroleum and gas pipelines and overhead electric transmission lines.

b. Propose mitigative measures to minimize or eliminate potential Project impacts to energy resources, as appropriate.

11. Socioeconomics

The EIS will:

a. Analyze the effects of a potential influx of construction workers and the potential increase in demand for local services interrelated with natural or physical environmental effects.

b. Propose mitigative measures to minimize or eliminate potential Project adverse impacts to social and economic resources, as appropriate.

12. Transportation Systems

The EIS will:

a. Evaluate the potential impacts of each alternative, including new rail line construction and operation, on the existing transportation network in the Project area, including vehicular delays at grade crossings.

b. Propose mitigative measures to minimize or eliminate potential Project impacts to transportation systems, as appropriate.

13. Cultural and Historic Resources

The EIS will:

a. Analyze the potential impacts to historic structures or districts previously recorded and determined potentially eligible, eligible, or listed on the National Register of Historic Places within or immediately adjacent to the right-of-way for the proposed rail alignments.

b. Evaluate the potential impacts of each alternative to archaeological sites previously recorded and either listed as unevaluated or determined potentially eligible, eligible, or listed on the National Register of Historic Places within the right-of-way for the alternative rail alignments and the no-action alternative.

c. Propose mitigative measures to minimize or eliminate potential Project impacts to cultural and historic resources, as appropriate.

14. Environmental Justice

The EIS will:

a. Evaluate the potential impacts of each alternative, including construction and operation of the rail lines, on local and regional minority populations and low-income populations.

b. Propose mitigative measures to minimize or eliminate potential Project impacts on environmental justice issues, as appropriate.

15. Cumulative Impacts

The EIS will address the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-federal) or person undertakes such actions.

By the Board, Victoria Rutson, Chief, Section of Environmental Analysis.

Anne K. Quinlan,

Acting Secretary.

[FR Doc. E8–2562 Filed 2–11–08; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network; Agency Information Collection Activities; Renewal Without Change of a Current Collection; Comment Request

AGENCY: Financial Crimes Enforcement Network (''FinCEN''), Treasury.

ACTION: Notice and request for comments.

SUMMARY: In order to comply with the requirements of the Paperwork Reduction Act of 1995, FinCEN intends to submit the information collection addressed in this notice for a three-year extension of approval by the Office of Management and Budget (OMB). OMB Control Number 1506–0043 currently covers the information collection addressed in this notice. Prior to submission of the extension request, FinCEN is soliciting comment on those information collections in 31 CFR 103.177, Prohibition on correspondent accounts for foreign shell banks; records concerning owners of foreign banks and agents for service of legal process.

DATES: Written comments should be received on or before April 14, 2008.

ADDRESSES: You may submit comments, identified by 1506–0043, by any of the following methods:

- Federal e-rulemaking portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- E-mail: *regcomments@fincen.gov.* Include OMB Control Number 1506–0043 in the subject line of the message.
- *Mail:* Department of the Treasury, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Include OMB Control Number 1506–0043 in the body of the text.

Instructions: It is preferable for comments to be submitted by electronic mail. Please submit comments by one method only. All submissions received must include the agency name and the Office of Management and Budget (OMB) control number for this rulemaking. All comments received will be posted without change to *http://www.fincen.gov,* including any personal information provided.

Inspection of comments: Comments may be inspected, between 10 a.m. and 4 p.m., in the FinCEN reading room in Vienna, VA. Persons wishing to inspect the comments submitted must request an appointment with the Disclosure Officer by telephoning (703) 905–5034 (Not a toll free call).

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory helpline at (800) 949–2732 and select Option 6.

SUPPLEMENTARY INFORMATION: The Bank Secrecy Act (''BSA''), Titles I and II of Public Law 91–508, as amended, codified at 12 U.S.C. 1829(b), 12 U.S.C. 1951–1959, and 31 U.S.C. *et seq.*, authorizes the Secretary of the Treasury, *inter alia,* to issue regulations requiring records and reports that are determined to have a high degree of usefulness in criminal, tax and regulatory matters. Title III of the USA PATRIOT Act of 2001, Public Law 107–56, included certain amendments to the anti-money laundering provisions of Title II of the BSA, 31 U.S.C. 5311 *et seq.*, which are intended to aid in the prevention, detection and prosecution of international money laundering and terrorist financing. Regulations implementing Title II of the BSA appear at 31 CFR part 103. The authority of the Secretary of the Treasury to administer Title II of the BSA has been delegated to the Director of FinCEN. The information collected and retained under the regulation addressed in this notice assist federal, state, and local law enforcement as well as regulatory authorities in the identification, investigation and prosecution of money laundering and other matters. In accordance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), and its implementing regulations, the following information is presented concerning the information collection below.

Title: Correspondent Accounts for Foreign Shell Banks; Recordkeeping and Termination of Correspondent Accounts for Foreign Banks (31 CFR 103.177).

OMB Number: 1506–0043.[1]

Abstract: Covered financial institutions are prohibited from maintaining correspondent accounts for foreign shell banks (31 CFR 103.177(a)(1)). Covered financial institutions that maintain correspondent accounts for foreign banks must maintain records of owner(s) of the foreign bank and the names and address of a person residing in the United States who is authorized to accept service of legal process for the foreign bank (31 CFR 103.177(a)(2)). Covered financial institutions may satisfy these requirements by using the sample certification and re-certification forms contained in Appendices A and B of 31 CFR 103. Records of documents relied upon by a financial institution for purposes of 31 CFR 103.177 must be maintained for at least five years after the date that the financial institution no longer maintains a correspondent account for such foreign bank (31 CFR 103.177(e)).

Current Action: There is no change to the existing regulations.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or for-profit institutions, and non-profit institutions.

Burden: The estimated average annual reporting burden associated with

[1] This collection was formerly assigned OMB Control number 1505–0184.

Appendix A is 20 hours per respondent; the estimated average annual reporting burden associated with Appendix B is 5 hours per respondent; and the estimated average recordkeeping burden associated with section 103.177(e) is 9 hours per recordkeeper.

The following paragraph applies to the collection of information addressed in this notice. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Records required to be retained under the BSA must be retained for five years. Generally, information collected pursuant to the BSA is confidential, but may be shared as provided by law with regulatory and law enforcement authorities.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance and purchase of services to provide information.

Dated: February 1, 2008.

James H. Freis, Jr.

Director, Financial Crimes Enforcement Network.

[FR Doc. E8–2505 Filed 2–11–08; 8:45 am]

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Federal Register

Tuesday,

February 12, 2008

Part II

Department of Health and Human Services

42 CFR Part 3

Patient Safety and Quality Improvement; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 3

RIN 0919–AA01

Patient Safety and Quality Improvement

AGENCY: Agency for Healthcare Research and Quality, Office for Civil Rights, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes regulations to implement certain aspects of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act). The proposed regulations establish a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for analysis of patient safety events. The proposed regulations also outline the requirements that entities must meet to become PSOs and the processes for the Secretary to review and accept certifications and to list PSOs.

In addition, the proposed regulation establishes the confidentiality protections for the information that is assembled and developed by providers and PSOs, termed ''patient safety work product'' by the Patient Safety Act, and the procedures for the imposition of civil money penalties for the knowing or reckless impermissible disclosure of patient safety work product.

DATES: Comments on the proposed rule will be considered if we receive them at the appropriate address, as provided below, no later than April 14, 2008.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Comments should include agency name and ''RIN 0919–AA01''.
- *Mail:* Center for Quality Improvement and Patient Safety, Attention: Patient Safety Act NPRM Comments, AHRQ, 540 Gaither Road, Rockville, MD 20850.
- *Hand Delivery/Courier:* Center for Quality Improvement and Patient Safety, Attention: Patient Safety Act NPRM Comments, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850.

Instructions: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or electronic mail. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document. Comments will be available for public inspection at the AHRQ Information Resources Center at the above-cited address between 8:30 a.m. and 5 p.m. Eastern Time on federal business days (Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Susan Grinder, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, (301) 427–1111 or (866) 403–3697.

SUPPLEMENTARY INFORMATION:

Public Participation

We welcome comments from the public on all issues set forth in this proposed rule to assist us in fully considering issues and developing policies. You can assist us by referencing the RIN number (RIN: 0919–0AA01) and by preceding your discussion of any particular provision with a citation to the section of the proposed rule being discussed.

A. Inspection of Public Comments

All comments (electronic, mail, and hand delivery/courier) received in a timely manner will be available for public inspection as they are received, generally beginning approximately 6 weeks after publication of this document, at the mail address provided above, Monday through Friday of each week from 8:30 a.m. to 5 p.m. To schedule an appointment to view public comments, call Susan Grinder, (301) 427–1111 or (866) 403–3697.

Comments submitted electronically will be available for viewing at the Federal eRulemaking Portal.

B. Electronic Comments

We will consider all electronic comments that include the full name, postal address, and affiliation (if applicable) of the sender and are submitted through the Federal eRulemaking Portal identified in the **ADDRESSES** section of this preamble. Copies of electronically submitted comments will be available for public inspection as soon as practicable at the address provided, and subject to the process described, in the preceding paragraph.

C. Mailed Comments and Hand Delivered/Couriered Comments

Mailed comments may be subject to delivery delays due to security procedures. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays. Comments mailed to the address indicated for hand or courier delivery may be delayed and could be considered late.

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F. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive in accordance with the methods described above and by the date specified in the **DATES** section of this preamble. When we proceed with a final rule, we will respond to comments in the preamble to that rule.

I. Background

A. Purpose and Basis

This proposed rule establishes the authorities, processes, and rules necessary to implement the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), (Pub. L. 109–41), that amended the Public Health Service Act (42 U.S.C. 299 *et seq.*) by inserting new sections 921 through 926, 42 U.S.C. 299b–21 through 299b–26.

Much of the impetus for this legislation can be traced to the publication of the landmark report, ''To

Err Is Human'' [1], by the Institute of Medicine in 1999 (Report). The Report cited studies that found that at least 44,000 people and potentially as many as 98,000 people die in U.S. hospitals each year as a result of preventable medical errors.[2] Based on these studies and others, the Report estimated that the total national costs of preventable adverse events, including lost income, lost household productivity, permanent and temporary disability, and health care costs to be between $17 billion and $29 billion, of which health care costs represent one-half.[3] One of the main conclusions was that the majority of medical errors do not result from individual recklessness or the actions of a particular group; rather, most errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent adverse events.[4] Thus, the Report recommended mistakes can best be prevented by designing the health care system at all levels to improve safety—making it harder to do something wrong and easier to do something right.[5]

As compared to other high-risk industries, the health care system is behind in its attention to ensuring basic safety.[6] The reasons for this lag are complex and varied. Providers are often reluctant to participate in quality review activities for fear of liability, professional sanctions, or injury to their reputations. Traditional state-based legal protections for such health care quality improvement activities, collectively known as peer review protections, are limited in scope: They do not exist in all States; typically they only apply to peer review in hospitals and do not cover other health care settings, and seldom enable health care systems to pool data or share experience between facilities. If peer review protected information is transmitted outside an individual hospital, the peer review privilege for that information is generally considered to be waived. This limits the potential for aggregation of a sufficient number of patient safety events to permit the identification of patterns that could suggest the underlying causes of risks and hazards that then can be used to improve patient safety.

The Report outlined a comprehensive strategy to improve patient safety by which public officials, health care providers, industry, and consumers could reduce preventable medical errors. The Report recommended that, in order to reduce medical errors appreciably in the U.S., a balance be struck between regulatory and market-based initiatives and between the roles of professionals and organizations. It recognized a need to enhance knowledge and tools to improve patient safety and break down legal and cultural barriers that impede such improvement.

Drawing upon the broad framework advanced by the Institute of Medicine, the Patient Safety Act specifically addresses a number of these long-recognized impediments to improving the quality, safety, and outcomes of health care services. For that reason, implementation of this proposed rule can be expected to accelerate the development of new, voluntary, provider-driven opportunities for improvement, increase the willingness of health care providers to participate in such efforts, and, most notably, set the stage for breakthroughs in our understanding of how best to improve patient safety.

These outcomes will be advanced, in large measure, through implementation of this proposed rule of strong Federal confidentiality and privilege protections for information that is patient safety work product under the Patient Safety Act. For the first time, there will now be a uniform set of Federal protections that will be available in all states and U.S. territories and that extend to all health care practitioners and institutional providers. These protections will enable all health care providers, including multi-facility health care systems, to share data within a protected legal environment, both within and across states, without the threat of information being used against the subject providers.

Pursuant to the Patient Safety Act, this proposed rule will also encourage the formation of new organizations with expertise in patient safety, known as patient safety organizations (PSOs), which can provide confidential, expert advice to health care providers in the analysis of patient safety events.[7] The confidentiality and privilege protections of this statute attach to ''patient safety work product.'' This term as defined in the Patient Safety Act and this proposed rule means that patient safety information that is collected or developed by a provider and reported to a PSO, or that is developed by a PSO when conducting defined ''patient safety activities,'' or that reveals the deliberations of a provider or PSO within a patient safety evaluation system is protected. Thus, the proposed rule will enable health care providers to protect their internal deliberations and analysis of patient safety information because this type of information is patient safety work product.

The statute and the proposed rule seek to ensure that the confidentiality provisions (as defined in these proposed regulations) will be taken seriously by making breaches of the protections potentially subject to a civil money penalty of up to $10,000. The combination of strong Federal protections for patient safety work product and the potential penalties for violation of these protections should give providers the assurances they need to participate in patient safety improvement initiatives and should spur the growth of such initiatives.

Patient safety experts have long recognized that the underlying causes of risks and hazards in patient care can best be recognized through the aggregation of significant numbers of individual events; in some cases, it may require the aggregation of thousands of individual patient safety events before underlying patterns are apparent. It is hoped that this proposed rule will foster routine reporting to PSOs of data on patient safety events in sufficient numbers for valid and reliable analyses. Analysis of such large volumes of patient safety events is expected to significantly advance our understanding of the patterns and commonalities in the underlying causes of risks and hazards in the delivery of patient care. These insights should enable providers to more effectively and efficiently target their efforts to improve patient safety.

We recognize that risks and hazards can occur in a variety of environments, such as inpatient, outpatient, long-term

[1] Institute of Medicine, ''*To Err is Human: Building a Safer Health System*'', 1999.

[2] *Id.* at 31.

[3] *Id.* at 42.

[4] *Id.* at 49–66.

[5] *Id.*

[6] *Id.* at 75.

[7] As we use the term, patient safety event means an incident that occurred during the delivery of a health care service and that harmed, or could have resulted in harm to, a patient. A patient safety event may include an error of omission or commission, mistake, or malfunction in a patient care process; it may also involve an input to such process (such as a drug or device) or the environment in which such process occurs. Our use of the term patient safety event in place of the more limited concept of medical error to describe the work that providers and PSOs may undertake reflects the evolution in the field of patient safety. It is increasingly recognized that important insights can be derived from the study of patient care processes and their organizational context and environment in order to prevent harm to patients. We note that patient safety in the context of this term also encompasses the safety of a person who is a subject in a research study conducted by a health care provider. In addition, the flexible concept of a patient safety event is applicable in any setting in which health care is delivered: A health care facility that is mobile (e.g., ambulance), fixed and free-standing (e.g., hospital), attached to another entity (e.g., school clinic), as well as the patient's home or workplace, whether or not a health care provider is physically present.

care, rehabilitation, research, or other health care settings. In many of these settings, patient safety analysis is a nascent enterprise that will benefit significantly from the routine, voluntary reporting and analysis of patient safety events. Accordingly, we strive in the proposed rule to avoid imposing limitations that might preclude innovative approaches to the identification of, and elimination of, risks and hazards in specific settings for the delivery of care, specific health care specialties, or in research settings. We defer to those creating PSOs and the health care providers that enter ongoing relationships with them to determine the scope of patient safety events that will be addressed.

Finally, we note that the statute is quite specific that these protections do not relieve a provider from its obligation to comply with other legal, regulatory, accreditation, licensure, or other accountability requirements that it would otherwise need to meet. The fact that information is collected, developed, or analyzed under the protections of the Patient Safety Act does not shield a provider from needing to undertake similar activities, if applicable, outside the ambit of the statute, so that the provider can meet its obligations with non-patient safety work product. The Patient Safety Act, while precluding other organizations and entities from requiring providers to provide them with patient safety work product, recognizes that the data underlying patient safety work product remains available in most instances for the providers to meet these other information requirements.

In summary, this proposed rule implements the Patient Safety Act and facilitates its goals by allowing the health care industry voluntarily to avail itself of this framework in the best manner it determines feasible. At the same time, it seeks to ensure that those who do avail themselves of this framework will be afforded the legal protections that Congress intended and that anyone who breaches those protections will be penalized commensurately with the violation.

B. Listening Sessions

We held three listening sessions for the general public (March 8, 13, and 16, 2006) which helped us better understand the thinking and plans of interested parties, including providers considering the use of PSO services and entities that anticipate establishing PSOs. As stated in the **Federal Register** notice 71 FR 37 (February 24, 2006) that announced the listening sessions, we do not regard the presentations or comments made at these sessions as formal comments and, therefore, they are not discussed in this document.

C. Comment Period

The comment period is sixty (60) days following the publication of the proposed rule.

II. Overview of Proposed Rule

We are proposing a new Part 3 to Title 42 of the Code of Federal Regulations to implement the Patient Safety Act. As described above, the Patient Safety Act is an attempt to address the barriers to patient safety and health care quality improvement activities in the U.S. In implementing the Patient Safety Act, this proposed rule encourages the development of provider-driven, voluntary opportunities for improving patient safety; this initiative is neither funded, nor controlled by the Federal Government.

Under the proposal, a variety of types of organizations—public, private, for-profit, and not-for-profit—can become PSOs, and offer their consultative expertise to providers regarding patient safety events and quality improvement initiatives. There will be a process for certification and listing of PSOs, which will be implemented by the Agency for Healthcare Research and Quality (AHRQ), and providers can work voluntarily with PSOs to obtain confidential, expert advice in analyzing the patient safety event and other information they collect or develop at their offices, facilities, or institutions. PSOs may also provide feedback and recommendations regarding effective strategies to improve patient safety as well as proven approaches for implementation of such strategies. In addition, to encourage providers to undertake patient safety activities, the regulation is very specific that patient safety work product is subject to confidentiality and privilege protections, and persons that breach the confidentiality provisions may be subject to a $10,000 civil money penalty, to be enforced by the Office for Civil Rights (OCR).

The provisions of this proposed rule greatly expand the potential for participation in patient safety activities. The proposal, among other things, enables providers across the health care industry to report information to a PSO and obtain the benefit of these new confidentiality and privilege protections. This proposal minimizes the barriers to entry for listing as a PSO by creating a review process that is both simple and efficient. As a result, we expect a broad range of organizations to seek listing by the Secretary as PSOs. Listing will not entitle these entities to Federal funding or subsidies, but it will enable these PSOs to offer individual and institutional providers the benefits of review and analysis of patient safety work product that is protected by strong Federal confidentiality and privilege protections.

Our proposed regulation will enable and assist data aggregation by PSOs to leverage the possibility of learning from numerous patient safety events across the health care system and to facilitate the identification and correction of systemic and other errors. For example, PSOs are required to seek contracts with multiple providers, and proposed Subpart C permits them, with certain limitations, to aggregate patient safety work product from their multiple clients and with other PSOs. In addition, the Secretary will implement other provisions of the Patient Safety Act that, independent of this proposed rule, require the Secretary to facilitate the development of a network of patient safety databases for the aggregation of nonidentifiable patient safety work product and the development of consistent definitions and common formats for collecting and reporting patient safety work product. These measures will facilitate a new level of data aggregation that patient safety experts deem essential to maximize the benefits of the Patient Safety Act.

The Patient Safety Act gives considerable attention to the relationship between it and the Standards for the Privacy of Individually Identifiable Health Information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA Privacy Rule). We caution that the opportunity for a provider to report identifiable patient safety work product to a PSO does not relieve a provider that is a HIPAA covered entity of its obligations under the HIPAA Privacy Rule. In fact, the Patient Safety Act indicates that PSOs are deemed to be business associates of providers that are HIPAA covered entities. Thus, providers who are HIPAA covered entities will need to enter into business associate agreements with PSOs in accordance with their HIPAA Privacy Rule obligations. If such a provider also chooses to enter a PSO contract, we believe that such contracts could be entered into simultaneously as an agreement for the conduct of patient safety activities. However, the Patient Safety Act does not require a provider to enter a contract with a PSO to receive the protections of the Patient Safety Act.

Proposed Subpart A, General Provisions, sets forth the purpose of the provisions and the definitions

applicable to the subparts that follow. Proposed Subpart B, PSO Requirements and Agency Procedures, sets forth the requirements for PSOs and describes how the Secretary will review, accept, revoke, and deny certifications for listing and continued listing of entities as PSOs and other required submissions. Proposed Subpart C, Confidentiality and Privilege Protections of Patient Safety Work Product, describes the provisions that relate to the confidentiality protections and permissible disclosure exceptions for patient safety work product. Proposed Subpart D, Enforcement Program, includes provisions that relate to activities for determining compliance, such as investigations of and cooperation by providers, PSOs, and others; the imposition of civil money penalties; and hearing procedures.

III. Section by Section Description of the Proposed Rule

A. Subpart A—General Provision

1. Proposed § 3.10—Purpose

The purpose of this proposed Part is to implement the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109–41), which amended the Public Health Service Act (42 U.S.C. 299 *et seq.*) by inserting new sections 921 through 926, 42 U.S.C. 299b–21 through 299b–26.

2. Proposed § 3.20—Definitions

Section 921 of the Public Health Service Act, 42 U.S.C. 299b–21, defines several terms, and our proposed rules would, for the most part, restate the law. In some instances, we propose to clarify definitions to fit within the proposed framework. We also propose some new definitions for convenience and to clarify the application and operation of this proposed rule. Moreover, we reference terms defined under the HIPAA Privacy Rule for ease of interpretation and consistency, given the overlap between the Patient Safety Act protections of patient-identifiable patient safety work product (discussed below) and the HIPAA Privacy Rule.

Proposed § 3.20 would establish the basic definitions applicable to this proposed rule, as follows:

AHRQ stands for the Agency for Healthcare Research and Quality in the U.S. Department of Health and Human Services (HHS). This definition is added for convenience.

ALJ stands for an Administrative Law Judge at HHS. This definition is added for convenience in describing the process for appealing civil money penalty determinations.

Board would mean the members of the HHS Departmental Appeals Board. This definition is added for convenience in providing for appeals of civil money penalty determinations.

Bona fide contract would mean (a) a written contract between a provider and a PSO that is executed in good faith by officials authorized to execute such contract; or (b) a written agreement (such as a memorandum of understanding or equivalent recording of mutual commitments) between a Federal, State, local, or Tribal provider and a Federal, State, local, or Tribal PSO that is executed in good faith by officials authorized to execute such agreement.

In addition to the primary interpretation of an enforceable contract under applicable law as proposed under paragraph (a) of this definition, we propose to make the scope of the term broad enough to encompass agreements between health care providers and PSOs that are components of Federal, State, local or Tribal governments or government agencies. Such entities could clearly perform the same data collection and analytic functions as performed by other providers and PSOs that the Patient Safety Act seeks to foster. Thus, paragraph (b) of the definition recognizes that certain government entities may not enter a formal contract with each other, but may only make a commitment with other agencies through the mechanism of some other type of agreement.

We note that proposed § 3.102(a)(2) incorporates the statutory restriction that a health insurance issuer and a component of a health insurance issuer may not become a PSO. That section also proposes to prohibit the listing of public and private entities that conduct regulatory oversight of health care providers, including accreditation and licensure.

Complainant would mean a person who files a complaint with the Secretary pursuant to proposed § 3.306.

Component Organization would mean an entity that is either: (a) A unit or division of a corporate organization or of a multi-organizational enterprise; or (b) a separate organization, whether incorporated or not, that is owned, managed or controlled by one or more other organizations (i.e., its parent organization(s)). We discuss our preliminary interpretation of the terms ''owned,'' ''managed,'' or ''controlled'' in the definition of parent organization. Multi-organizational enterprise, as used here, means a common business or professional undertaking in which multiple entities participate as well as governmental agencies or Tribal entities in which there are multiple components.[8]

We anticipate that PSOs may be established by a wide array of health-related organizations and quality improvement enterprises, including hospitals, nursing homes and health care provider systems, health care professional societies, academic and commercial research organizations, Federal, State, local, and Tribal governmental units that are not subject to the proposed restriction on listing in proposed § 3.102(a)(2), as well as joint undertakings by combinations of such organizations. One effect of defining component organization as we propose is that, pursuant to section 924 of the Patient Safety Act, 42 U.S.C. 299b–24, all applicant PSOs that fall within the scope of the definition of component organization must certify to the separation of confidential patient safety work product and staff from the rest of any organization or multi-organizational enterprise of which they (in the conduct of their work) are a part. Component organizations must also certify that their stated mission can be accomplished without conflicting with the rest of their parent organization(s).

A subsidiary corporation may, in certain circumstances, be viewed as part of a multi-organizational enterprise with its parent corporation and would be so regarded under the proposed regulation. Thus, an entity, such as a PSO that is set up as a subsidiary by a hospital chain, would be considered a component of the corporate chain and a component PSO for purposes of this proposed rule. Considering a subsidiary of a corporation to be a ''component'' of its parent organization may seem contrary to the generally understood separateness of a subsidiary in its corporate relationship with its parent.[9]

[8] The concept of multi-organizational enterprise as used in this regulation, in case law, and in a legal reference works such as *Blumberg on Corporate Groups, § 6.04 (2d ed. 2007 Supplement)* refers to multi-organizational undertakings with separate corporations or organizations that are integrated in a common business activity. The component entities are often, but not necessarily, characterized by interdependence and some form of common control, typically by agreement. Blumberg notes that health care providers increasingly are integrated in various forms of multi-organizational enterprises.

[9] Corporations are certain types of organizations that are given legal independence and rights, (e.g. the right to litigate). Subsidiary corporations are corporations in which a majority of the shares are owned by another corporation, known as a parent corporation. Thus, subsidiaries are independent corporate entities in a formal legal sense, yet, at the same time, they are controlled, to some degree, by their parent by virtue of stock ownership and control. Both corporations and subsidiaries are legal constructs designed to foster investment and

Continued

That is, where two corporate entities are legally separate, one entity would ordinarily not be considered a component of the other entity, even when that other entity has a controlling interest or exercises some management control. However, we have preliminarily determined that viewing a subsidiary entity that seeks to be a PSO as a component of its parent organization(s) would be consistent with the objectives of the section on certifications required of component organizations in the Patient Safety Act and appears to be consistent with trends in the law discussed below. We invite comment on our interpretation.

Corporations law or ''entity law,'' which emphasizes the separateness and distinct rights and obligations of a corporation, has been supplemented by the development of ''relational law'' when necessary (e.g., to address evolving organizational arrangements such as multi-organizational enterprises). To determine rights and obligations in these circumstances, courts weigh the relationships of separate corporations that are closely related by virtue of participating in the same enterprise, (i.e., a common chain of economic activity fostering and characterized by interdependence).[10] There has been a growing trend in various court decisions to attribute legal responsibilities based on actual behavior in organizational relationships, rather than on corporate formalities.

We stress that neither the statute nor the proposed regulation imposes any legal responsibilities, obligations, or liability on the organization(s) of which a component PSO is a part. The focus of the Patient Safety Act and the regulation is principally on the entity that voluntarily seeks listing by the Secretary as a PSO.

We note that two of the three certifications that the Patient Safety Act and the proposed regulation requires component entities to make—relating to the security and confidentiality of patient safety work product—are essentially duplicative of attestations that are required of all entities seeking listing or continued listing as a PSO (certifications made under section 924(a)(1)(A) and (a)(2)(A) of the Public Health Service Act, 42 U.S.C. 299b–24(a)(1)(A) and (a)(2)(A) with respect to patient safety activities described in section 921(5)(E) and (F) of the Public Health Service Act, 42 U.S.C. 299b–21(5)(E) and (F)). That is, under the Patient Safety Act, all PSOs have to attest that they have in place policies and procedures to, and actually do, perform patient safety activities, which include the maintenance of procedures to preserve patient safety work product confidentiality and the provision of appropriate security measures for patient safety work product. The overlapping nature of these confidentiality and security requirements on components suggests heightened congressional concern and emphasis regarding the need to maintain a strong ''firewall'' between a component PSO and its parent organization, which might have the opportunity and potential to access sensitive patient safety work product the component PSO assembles, develops, and maintains. A similar concern arises in the context of a PSO that is a unit of a corporate parent, a subsidiary or an entity affiliated with other organizations in a multi-organizational enterprise.

Requiring entities seeking listing to disclose whether they have a parent organization or are part of a multi-organizational enterprise does not involve ''piercing the corporate veil'' as discussed in the footnote above. The Department would not be seeking this information to hold a parent liable for actions of the PSO, but to ensure full disclosure to the Department about the organizational relationships of an entity seeking to be listed as a PSO. Accordingly, we propose that an entity seeking listing as a PSO must do so as a component organization if it has one or more parent organizations (as described here and in the proposed definition of that term) or is part of a multi-organizational enterprise, and it must provide the names of its parent entities. If it has a parent or several parent organizations, as defined by the proposed regulation, the entity seeking to be listed must provide the additional certifications mandated by the statute and by the proposed regulation at § 3.102(c) to maintain the separateness of its patient safety work product from its parent(s) and from other components or affiliates[11] of its parent(s). Such certifications are consistent with the above-cited body of case law that permits and makes inquiries about organizational relationships and practices for purposes of carrying out statutes and statutory objectives.

It may be helpful to illustrate how a potential applicant for listing should apply these principles in determining whether to seek listing as a component PSO. The fundamental principle is that if there is a parent organization relationship present and the entity is not prohibited from seeking listing by proposed § 3.102(a)(2), the entity must seek listing as a component PSO. In determining whether an entity must seek listing as a component organization, we note that it does not matter whether the entity is a component of a provider or a non-provider organization and, if it is a component of a provider organization, whether it will undertake patient safety activities for the parent organization's providers or providers that have no relationship with its parent organization(s). The focus here is primarily on establishing the separateness of the entity's operation from any type of parent organization. Examples of entities that would need to seek listing as a component organization include: A division of a provider or non-provider organization; a subsidiary entity created by a provider or non-provider organization; or a joint venture created by several organizations (which could include provider organizations, non-provider organizations, or a mix of such organizations) where any or all of the organizations have a measure of control over the joint venture.

Other examples of entities that would need to seek listing as a component PSO include: a division of a nursing home chain; a subsidiary entity created by a large academic health center or health system; or a joint venture created by several organizations to seek listing as a PSO where any or all of the organizations have a measure of control over the joint venture.

Component PSO would mean a PSO listed by the Secretary that is a component organization.

Confidentiality provisions would mean any requirement or prohibition concerning confidentiality established by Sections 921 and 922(b)–(d), (g) and (i) of the Public Health Service Act, 42

commerce by limiting entrepreneurial risks and corporate liabilities. In recognition of the legitimate utility of these objectives, courts have generally respected the separateness of parent corporations and subsidiaries, (e.g., courts do not ordinarily allow the liabilities of a subsidiary to be attributed to its parent corporation, despite the fact that by definition, parent corporations have a measure of control over a subsidiary). However, courts have looked behind the separate legal identities that separate parent and subsidiary to impose liability when individuals in litigation can establish that actual responsibility rests with a parent corporation by virtue of the degree and manner in which it has exercised control over its subsidiary. Under these circumstances, courts permit ''the corporate veil to be pierced.''

[10] *See Phillip I. Blumberg Et Al., Blumberg On Corporate Groups §§ 6.01 and 6.02.*

[11] Corporate affiliates are commonly controlled corporations; sharing a corporate parent, they are sometimes referred to as sister corporations. Separate corporations that are part of a multi-organizational enterprise are also referred to by the common terms ''affiliates'' or ''affiliated organizations''.

U.S.C. 299b–21 and 299b–22(b)–(d), (g) and (i), and the proposed provisions, at §§ 3.206 and 3.208, by which we propose to implement the prohibition on disclosure of identifiable patient safety work product. We proposed to define this new term to provide an easy way to reference the provisions in the Patient Safety Act and in the proposed rule that implements the confidentiality protections of the Patient Safety Act for use in the enforcement and penalty provisions of this proposed rule. We found this a useful approach in the HIPAA Enforcement Rule, where we defined ''administrative simplification provision'' for that purpose. In determining how to define ''confidentiality provisions'' that could be violated, we considered the statutory enforcement provision at section 922(f) of the Public Health Service Act, 42 U.S.C. 299b–22(f), which incorporates by reference section 922(b) and (c).[12] Thus, the enforcement authority clearly implicates sections 922(b) and (c) of the Patient Safety Act, 42 U.S.C. 299b–22(b) and (c), which are implemented in proposed § 3.206. Section 922(d) of the Patient Safety Act, 42 U.S.C. 299b–22(d), is entitled the ''Continued Protection of Information After Disclosure'' and sets forth continued confidentiality protections for patient safety work product after it has been disclosed under section 922(c) of the Public Health Service Act, 42 U.S.C. 299b–22(c), with certain exceptions. Thus, section 922(d) of the Public Health Service Act, 42 U.S.C. 299b–22(d), is a continuation of the confidentiality protections provided for in section 922(b) of the Public Health Service Act, 42 U.S.C. 299b–22(b). Therefore, we also consider the continued confidentiality provision at proposed § 3.208 herein to be one of the confidentiality provisions. In addition, our understanding of these provisions is based on the rule of construction in section 922(g) of the Public Health Service Act, 42 U.S.C. 299b–22(g), and the clarification with respect to HIPAA in section 922(i) of the Public Health Service Act, 42 U.S.C. 299b–22(i); accordingly, these provisions are included in the definition.

In contrast to the confidentiality provisions, the privilege provisions in the Patient Safety Act will be enforced by the tribunals or agencies that are subject to them; the Patient Safety Act does not authorize the imposition of civil money penalties for breach of such provisions. We note, however, that to the extent a breach of privilege is also a breach of confidentiality, the Secretary would enforce the confidentiality breach under 42 U.S.C. 299b–22(f).

Disclosure would mean the release, transfer, provision of access to, or divulging in any other manner of patient safety work product by a person holding patient safety work product to another person. An impermissible disclosure (i.e., a disclosure of patient safety work product in violation of the confidentiality provisions) is the action upon which potential liability for a civil money penalty rests. Generally, if the person holding patient safety work product is an entity, disclosure occurs when the information is shared with another entity or a natural person outside the entity. We do not propose to hold entities liable for uses of the information within the entity, (i.e., when this information is exchanged or shared among the workforce members of the entity) except as noted below concerning component PSOs. If a natural person holds patient safety work product, except in the capacity as a workforce member, a disclosure occurs whenever exchange occurs to any other person or entity. In light of this definition, we note that a disclosure to a contractor that is under the direct control of an entity (i.e., a workforce member) would be a use of the information within the entity and, therefore, not a disclosure for which a permission is needed. However, a disclosure to an independent contractor would not be a disclosure to a workforce member, and thus, would be a disclosure for purposes of this proposed rule and the proposed enforcement provisions under Subpart D.

For component PSOs, we propose to recognize as a disclosure the sharing or transfer of patient safety work product outside of the legal entity, as described above, and between the component PSO and the rest of the organization (i.e., parent organization) of which the component PSO is a part. The Patient Safety Act demonstrates a strong desire for the separation of patient safety work product between a component PSO and the rest of the organization. See section 924(b)(2) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(2). Because we propose to recognize component organizations as component PSOs which exist within, but distinct from, a single legal entity, and such a component organization as a component PSO would be required to certify to limit access to patient safety work product under proposed § 3.102(c), the release, transfer, provision of access to, or divulging in any other manner of patient safety work product from a component PSO to the rest of the organization will be recognized as a disclosure for purposes of this proposed rule and the proposed enforcement provisions under Subpart D.

We considered whether or not we should hold entities liable for disclosures that occur within that entity (uses) by defining disclosure more discretely, (i.e., as between persons within an entity). If we were to define disclosure in this manner, it may promote better safeguarding against inappropriate uses of patient safety work product by providers and PSOs. It may also allow better control of uses by third parties to whom patient safety work product is disclosed, and it would create additional enforcement situations which could lead to additional potential civil money penalties. We note that HIPAA authorized the Department to regulate both the uses and disclosures of individually identifiable health information and, thus, the HIPAA Privacy Rule regulates both the uses and disclosures of such information by HIPAA covered entities. See section 264(b) and (c)(1) of HIPAA, Public Law 104–191. The Patient Safety Act, on the other hand, addresses disclosures and authorizes the Secretary to penalize disclosures of patient safety work product.

Nonetheless, we do not propose to regulate the use, transfer or sharing by internal disclosure, of patient safety work product within a legal entity. We also decline to propose to regulate uses because we would consider regulating uses within providers and PSOs to be intrusive into their internal affairs. This would be especially the case given that this is a voluntary program. Moreover, we do not believe that regulating uses would further the statutory goal of facilitating the sharing of patient safety work product with PSOs. In other words, regulating uses would not advance the ability of any entity to share patient safety work product for patient safety activities. Finally, we presume that there are sufficient incentives in place for providers and PSOs to prudently manage the uses of sensitive patient safety work product.

[12] Section 922(f) of the Public Health Service Act, 42 U.S.C. 299b–22(f), states that ''subject to paragraphs (2) and (3), a person who discloses identifiable patient safety work product in knowing or reckless violation of subsection (b) shall be subject to a civil money penalty of not more than $10,000 for each act constituting such violation'' (emphasis added). Subsection (b) of section 922 of the Public Health Service Act, 42 U.S.C. 299b–22(b), is entitled, ''Confidentiality of Patient Safety Work Product'' and states, ''Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be confidential and shall not be disclosed'' (emphasis added). Section 922(c) of the Public Health Service Act, 42 U.S.C. 299b–22(c), in turn, contains the exceptions to confidentiality and privilege protections.

We are not regulating uses, whether in a provider, PSO, or any other entity that obtains patient safety work product. Because we are not proposing to regulate uses, there will be no federal sanction based on use of this information. If a provider or other entity wants to limit the uses or further disclosures (beyond the regulatory permissions) by a PSO or any future recipient, a disclosing entity is free to do so by contract. See section 922(g)(4) of the Public Health Service Act, 42 U.S.C. 299b–22(g)(4), and proposed § 3.206(e). We seek comment about whether this strikes the right balance.

The proposed definition mirrors the definition of disclosure used in the HIPAA Privacy Rule concerning disclosures of protected health information. Although we do not propose to regulate the use of patient safety work product, HIPAA covered entities that possess patient safety work product which contains protected health information must comply with the use and disclosure requirements of the HIPAA Privacy Rule with respect to the protected health information. Patient safety work product containing protected health information could only be used in accordance with the HIPAA Privacy Rule use permissions, including the minimum necessary requirement.

Entity would mean any organization, regardless of whether the organization is public, private, for-profit, or not-for-profit. The statute permits any entity to seek listing as a PSO by the Secretary except a health insurance issuer and any component of a health insurance issuer and § 3.102(a)(2) proposes, in addition, to prohibit public or private sector entities that conduct regulatory oversight of providers.

Group health plan would mean an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 (ERISA) to the extent that the plan provides medical care (as defined in paragraph (2) of section 2791(a) of the Public Health Service Act, 42 U.S.C. 300gg–91(a)(1)) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. Section 2791(b)(2) of the Public Health Service Act, 42 U.S.C. 300gg–91(b)(2) excludes group health plans from the defined class of 'health insurance issuer.' Therefore, a group health plan may establish a PSO unless the plan could be considered a component of a health insurance issuer, in which case such a plan would be precluded from being a PSO by the Patient Safety Act.

Health insurance issuer would mean an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in 42 U.S.C. 300gg–91(b)(3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of 29 U.S.C. 1144(b)(2)). The term, as defined in the Public Health Service Act, does not include a group health plan.

Health maintenance organization would mean (1) a Federally qualified health maintenance organization (as defined in 42 U.S.C. 300e(a)); (2) an organization recognized under State law as a health maintenance organization; or (3) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization. Because the ERISA definition relied upon by the Patient Safety Act includes health maintenance organizations in the definition of health insurance issuer, an HMO may not be, control, or manage the operation of a PSO.

HHS stands for the United States Department of Health and Human Services. This definition is added for convenience.

HIPAA Privacy Rule would mean the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), at 45 CFR Part 160 and Subparts A and E of Part 164.

Identifiable Patient Safety Work Product would mean patient safety work product that:

(1) Is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

(2) Constitutes individually identifiable health information as that term is defined in the HIPAA Privacy Rule at 45 CFR 160.103; or

(3) Is presented in a form and manner that allows the identification of an individual who in good faith reported information directly to a PSO, or to a provider with the intention of having the information reported to a PSO (''reporter'').

Identifiable patient safety work product is not patient safety work product that meets the nonidentification standards proposed for ''nonidentifiable patient safety work product''.

Nonidentifiable Patient Safety Work Product would mean patient safety work product that is not identifiable in accordance with the nonidentification standards proposed at § 3.212. Because the privilege and confidentiality protections of the Patient Safety Act and this Part do not apply to nonidentifiable patient safety work product once disclosed, the restrictions and data protection rules in this proposed rule phrased as pertaining to patient safety work product generally only apply to identifiable patient safety work product.

OCR stands for the Office for Civil Rights in HHS. This definition is added for convenience.

Parent organization would mean a public or private sector organization that, alone or with others, either owns a provider entity or a component PSO, or has the authority to control or manage agenda setting, project management, or day-to-day operations of the component, or the authority to review and override decisions of a component PSO. We have not proposed to define the term ''owns.'' We propose to use the term ''own a provider entity'' to mean a governmental agency or Tribal entity that controls or manages a provider entity as well as an organization having a controlling interest in a provider entity or a component PSO, for example, owning a majority or more of the stock of the owned entity, and expressly ask for comment on whether our further definition of controlling interest as follows below is appropriate.

Under the proposed regulation, if an entity that seeks to be a PSO has a parent organization, that entity will be required to seek listing as a component PSO and must provide certifications set forth in proposed § 3.102(c), which indicate that the entity maintains patient safety work product separately from the rest of the organization(s) and establishes security measures to maintain the confidentiality of patient safety work product, the entity does not make an unauthorized disclosure of patient safety work product to the rest of the organization(s), and the entity does not create a conflict of interest with the rest of the organization(s).

Traditionally, a parent *corporation* is defined as a corporation that holds a controlling interest in one or more subsidiaries. By contrast, parent *organization,* as used in this proposed rule, is a more inclusive term and is not limited to definitions used in corporations law. Accordingly, the proposed definition emphasizes a parent organization's control (or influence) over a PSO that may or may not be based on stock ownership.[13] Our

[13] *Cf.* 17 CFR 240.12b–2 (defining ''control'' broadly as ''* * * the power to direct or cause the direction of the management and policies of an * * * [entity] whether through the ownership of voting securities, by contract, or otherwise.'')

approach to interpreting the statutory reference in section 924(b)(2) of the Patient Safety Act, 42 U.S.C. 299b–24(b)(2) to ''another organization'' in which an entity is a ''component'' (i.e., a ''parent organization'') is analogous to the growing attention in both statutory and case law, to the nature and conduct of business organizational relationships, including multi-organizational enterprises. As discussed above in the definition of ''component,'' the emphasis on actual organizational control, rather than the organization's structure, has numerous legal precedents in legislation implementing statutory programs and objectives and courts upholding such programs and objectives.[14] Therefore, the definition of a ''parent organization,'' as used in the proposed regulation would encompass an affiliated *organization* that participates in a common enterprise with an entity seeking listing, and that owns, manages or exercises control over the entity seeking to be listed as a PSO. As indicated above, affiliated *corporations* have been legally defined to mean those who share a corporate parent or are part of a common corporate enterprise.[15]

Parent organization is defined to include affiliates primarily in recognition of the prospect that otherwise unrelated organizations might affiliate to jointly establish a PSO. We can foresee such an enterprise because improving patient safety through expert analysis of aggregated patient safety data could logically be a common and efficient objective shared by multiple potential cofounders of a PSO. It is fitting, in our view, that a component entity certify, as we propose in § 3.102(c), that there is ''no conflict'' between its mission as a PSO and all of the rest of the parent or affiliated organizations that undertake a jointly sponsored PSO enterprise.[16] Similarly, it is also appropriate that the additional certifications required of component entities in proposed § 3.102(c) regarding separation of patient safety work product and the use of separate staff be required of an entity that has several co-founder parent organizations that exercise ownership, management or control, (i.e. to assure that the intended ''firewalls'' exist between the component entity and the rest of any affiliated organization that might exercise ownership, management or control over a PSO).

To recap this part of the discussion, we would consider an entity seeking listing as a PSO to have a parent organization, and such entity would seek listing as a component organization, under the following circumstances: (a) The entity is a unit in a corporate organization or a controlling interest in the entity is owned by another corporation; or (b) the entity is a distinct organizational part of a multi-organizational enterprise and one or more affiliates in the enterprise own, manage, or control the entity seeking listing as a PSO. An example of an entity described in (b) would be an entity created by a joint venture in which the entity would be managed or controlled by several co-founding parent organizations.

The definition of provider in the proposed rule (which will be discussed below) includes the parent organization of any provider entity. Correspondingly, our definition of parent organization includes any organization that ''owns a provider entity.'' This is designed to provide an option for the holding company of a corporate health care system to enter a multi-facility or system-wide contract with a PSO.

Patient Safety Act would mean the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109–41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 *et seq.*) by inserting a new Part C, sections 921 through 926, which are codified at 42 U.S.C. 299b–21 through 299b–26.

Patient safety activities would mean the following activities carried out by or on behalf of a PSO or a provider:

(1) Efforts to improve patient safety and the quality of health care delivery;

(2) The collection and analysis of patient safety work product;

(3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;

(4) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;

(5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product;

(6) The provision of appropriate security measures with respect to patient safety work product;

(7) The utilization of qualified staff; and

(8) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

This definition is taken from the Patient Safety Act. See section 921(5) of the Public Health Service Act, 42 U.S.C. 299b–21(5). Patient safety activities is used as a key reference term for other provisions in the proposed rule and those provisions provide descriptions related to patient safety activities. See proposed requirements for PSOs at §§ 3.102 and 3.106 and the proposed confidentiality disclosure permission at § 3.206(b)(4).

Patient safety evaluation system would mean the collection, management, or analysis of information for reporting to or by a PSO. The patient safety evaluation system is a core concept of the Patient Safety Act through which information, including data, reports, memoranda, analyses, and/or written or oral statements, is collected, maintained, analyzed, and communicated. When a provider engages in patient safety activities for the purpose of reporting to a PSO or a PSO engages in these activities with respect to information for patient safety purposes, a patient safety evaluation system exists regardless of whether the provider or PSO has formally identified a ''patient safety evaluation system''. For example, when a provider collects information for the purpose of reporting to a PSO and reports the information to a PSO to generate patient safety work product, the provider is collecting and reporting through its patient safety evaluation system (see definition of *patient safety work product*). Although we do not propose to require providers or PSOs formally to identify or define their patient safety evaluation system—because such systems exist by virtue of the providers or PSOs undertaking certain patient safety activities—a patient safety evaluation system can be

[14] *Blumberg on Corporate Groups § 13* notes that, where applications for licenses are in a regulated industry, information is required by states about the applicant as well as corporate parents, subsidiaries and affiliates. In the proposed regulation, pursuant to the Patient Safety Act, information about parent organizations with potentially conflicting missions would be obtained to ascertain that component entities seeking to be PSOs have measures in place to protect the confidentiality of patient safety work product and the independent conduct of impartial scientific analyses by PSOs.

[15] See for example the definition of affiliates in regulations jointly promulgated by the Comptroller of the Currency, the Federal Reserve board, the FDIC, and the Office of Thrift Supervision to implement privacy provisions of Gramm Leach Bliley legislation using provisions of the Fair Credit Reporting Act (dealing with information sharing among affiliates): ''any company that is related or affiliated by common ownership, or affiliated by corporate control or common corporate control with another company.'' Blumberg, supra note 2, at § 122.09[A] (citing 12 CFR pt.41.3, 12 CFR pt.222.3(1), 12 CFR pt.334.3(b) and 12 CFR pt.571.3(1) (2004)).

[16] We note that the certifications from a jointly established PSO could be supported or substantiated with references to protective procedural or policy walls that have been established to preclude a conflict of these organizations' other missions with the scientific analytic mission of the PSO.

formally designated by a provider or PSO to establish a secure space in which these activities may take place.

The formal identification or designation of a patient safety evaluation system could give structure to the various functions served by a patient safety evaluation system. These possible functions are:

1. For reporting information by a provider to a PSO in order to generate patient safety work product and to protect the fact of reporting such information to a PSO (see section 921(6) and (7)(A)(i)(I) of the Public Health Service Act, 42 U.S.C. 299b–21(6) and (7)(A)(i)(I));

2. For communicating feedback concerning patient safety events between PSOs and providers (see section 921(5)(H) of the Public Health Service Act, 42 U.S.C. 299b–21(5)(H));

3. For creating and identifying the space within which deliberations and analyses of information and patient safety work product are conducted (see section 921(7)(A)(ii) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(A)(ii));

4. For separating patient safety work product and information collected, maintained, or developed for reporting to a PSO distinct and apart from information collected, maintained, or developed for other purposes (see section 921(7)(B)(ii) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(B)(ii)); and,

5. For identifying patient safety work product to maintain its privileged status and confidentiality, and to avoid impermissible disclosures (see section 922(b) of the Public Health Service Act, 42 U.S.C. 299b–22(b)).

A provider or PSO need not engage in all of the above-mentioned functions in order to establish or maintain a patient safety evaluation system. A patient safety evaluation system is flexible and scalable to the individual needs of a provider or PSO and may be modified as necessary to support the activities and level of engagement in the activities by a particular provider or PSO.

Documentation. Because a patient safety evaluation system is critical in identifying and protecting patient safety work product, we encourage providers and PSOs to document what constitutes their patient safety evaluation system. We recommend that providers and PSOs consider documenting the following:

- How information enters the patient safety evaluation system;
- What processes, activities, physical space(s) and equipment comprise or are used by the patient safety evaluation system;
- Which personnel or categories of personnel need access to patient safety work product to carry out their duties involving operation of, or interaction with the patient safety evaluation system, and for each such person or category of persons, the category of patient safety work product to which access is needed and any conditions appropriate to such access; and,
- What procedures or mechanisms the patient safety evaluation system uses to report information to a PSO or disseminate information outside of the patient safety evaluation system.

A documented patient safety evaluation system, as opposed to an undocumented or poorly documented patient safety evaluation system, may accrue many benefits to the operating provider or PSO. Providers or PSOs that have a documented patient safety evaluation system will have substantial proof to support claims of privilege and confidentiality when resisting requests for production of, or subpoenas for, information constituting patient safety work product or when making requests for protective orders against requests or subpoenas for such patient safety work product. Documentation of a patient safety evaluation system will enable a provider or PSO to provide supportive evidence to a court when claiming privilege protections for patient safety work product. This may be particularly critical since the same activities can be done inside and outside of a patient safety evaluation system.

A documented and established patient safety evaluation system also gives notice to employees of the privileged and confidential nature of the information within a patient safety evaluation system in order to generate awareness, greater care in handling such information and more caution to prevent unintended or impermissible disclosures of patient safety work product. For providers with many employees, an established and documented patient safety evaluation system can serve to separate access to privileged and confidential patient safety work product from employees that have no need for patient safety work product. Documentation can serve to limit access by non-essential employees. By limiting who may access patient safety work product, a provider may reduce its exposure to the risks of inappropriate disclosures.

Given all of the benefits, documentation of a patient safety evaluation system would be a prudent business practice. Moreover, as part of our enforcement program, we would expect entities to be following sound business practices in maintaining adequate documentation regarding their patient safety evaluation systems to demonstrate their compliance with the confidentiality provisions. Absent this type of documentation, it may be difficult for entities to satisfy the Secretary that they have met and are in compliance with their confidentiality obligations. While we believe it is a sound and prudent business practice, we have not required a patient safety evaluation system to be documented, and we do not believe it is required by the Patient Safety Act. We seek comment as to these issues.

Patient Safety Organization (PSO) would mean a private or public entity or component thereof that is listed as a PSO by the Secretary in accordance with proposed § 3.102.

Patient Safety Work Product is a defined term in the Patient Safety Act that identifies the information to which the privilege and confidentiality protections apply. This proposed rule imports the statutory definition of patient safety work product specifically for the purpose of implementing the confidentiality protections under the Patient Safety Act. The proposed rule provides that, with certain exceptions, patient safety work product would mean any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material) (A) which could result in improved patient safety, health care quality, or health care outcomes and either (i) is assembled or developed by a provider for reporting to a PSO and is reported to a PSO; or (ii) is developed by a PSO for the conduct of patient safety activities; or (B) which identifies or constitutes the deliberations or analysis of, or identifies the fact of reporting pursuant to, a patient safety evaluation system. The proposed rule excludes from patient safety work product a patient's original medical record, billing and discharge information, or any other original patient or provider information and any information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a PSO does not by reason of its reporting become patient safety work product. The separately collected and maintained information remains available, for example, for public health reporting or disclosures pursuant to court order. The information contained in a provider's or PSO's patient safety evaluation system is protected, would be privileged and confidential, and may not be disclosed absent a statutory or regulatory permission.

What can become patient safety work product. The definition of patient safety work product lists the types of information that are likely to be exchanged between a provider and PSO to generate patient safety work product: ''Any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements'' (collectively referred to below as ''information'' for brevity). Congress intended the fostering of robust patient safety evaluation systems for exchanges between providers and PSOs. We expect this expansive list will maximize provider flexibility in operating its patient safety evaluation system by enabling the broadest possible incorporation and protection of information by providers and PSOs.

In addition, information must be collected or developed for the purpose of reporting to a PSO. Records collected or developed for a purpose other than for reporting to a PSO, such as to support internal risk management activities or to fulfill external reporting obligations, cannot become patient safety work product. However, copies of information collected for another purpose may become patient safety work product if, for example, the copies are made for the purpose of reporting to a PSO. This issue is discussed more fully below regarding information that cannot become patient safety work product.

When information is reported by a provider to a PSO or when a PSO develops information for patient safety activities, the definition assumes that the protections apply to information that ''could result in improved patient safety, health care quality, or health care outcomes.'' This phrase imposes few practical limits on the type of information that can be protected since a broad range of clinical and non-clinical factors could have a beneficial impact on the safety, quality, or outcomes of patient care. Because the Patient Safety Act does not impose a narrow limitation, such as requiring information to relate solely, for example, to particular adverse or ''sentinel'' incidents or even to the safety of patient care, we conclude Congress intended providers to be able to cast a broad net in their data gathering and analytic efforts to identify causal factors or relationships that might impact patient safety, quality and outcomes. In addition, we note that the phrase ''could result in improved'' requires only potential utility, not proven utility, thereby allowing more information to become patient safety work product.

How information becomes patient safety work product. Paragraphs (1)(i)(A), (1)(i)(B), and (1)(ii) of the proposed regulatory definition indicate three ways for information to become patient safety work product and therefore subject to the confidentiality and privilege protections of the Patient Safety Act.

Information assembled or developed and reported by providers. By law and as set forth in our proposal, information that is assembled or developed by a provider for the purpose of reporting to a PSO and is reported to a PSO is patient safety work product. Section 921(7)(A)(i)(I) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(A)(i)(I).

As noted, to become patient safety work product under this section of the definition, information must be reported by a provider to a PSO. For purposes of paragraph (1)(i)(A) of this definition, ''reporting'' generally means the actual transmission or transfer of information, as described above, to a PSO. We recognize, however, that requiring the transmission of every piece of paper or electronic file to a PSO could impose significant transmission, management, and storage burdens on providers and PSOs. In many cases, providers engaged in their own investigations may desire to avoid continued transmission of additional related information as its work proceeds.

To alleviate the burden of reporting every piece of information assembled by a provider related to a particular patient safety event, we are interested in public comment regarding an alternative for providers that have established relationships with PSOs. We note that the reporting and generation of patient safety work product does not require a contract or any other relationship for a PSO to receive reports from a provider, for a PSO to examine patient safety work product, or for a PSO to provide feedback to a provider based upon the examination of reported information. Nonetheless, we anticipate that providers who are committed to patient safety improvements will establish a contractual or similar relationship with a PSO to report and receive feedback about patient safety incidents and adverse events. Such a contract or relationship would provide a basis to allow providers and PSOs to establish customized alternative arrangements for reporting.

For providers that have established contracts with PSOs for the review and receipt of patient safety work product, we seek comment on whether a provider should be able to ''report'' to the PSO by providing its contracted PSO access to any information it intends to report (i.e., ''functional reporting''). For example, a provider and a PSO may establish, by contract, that information put into a database shared by the provider and the PSO is sufficient to report information to the PSO in lieu of the actual transmission requirement. We believe that functional reporting would be a valuable mechanism for the efficient reporting of information from a provider to a PSO. We are seeking public comment about what terms and conditions may be necessary to provide access to a PSO to be recognized as functional reporting. We also seek comment about whether this type of functional reporting arrangement should only be available for subsequent related information once an initial report on a specific topic or incident has been transmitted to a PSO.

We do not intend a PSO to have an unfettered right of access to any provider information. Providers and PSOs are free to engage in alternative reporting arrangements under the proposed rule, and we solicit comments on the appropriate lines to be drawn around the arrangements that should be recognized under the proposed rule. However, our proposals should not be construed to suggest or propose that a PSO has a superior right to access information held by a provider based upon a reporting relationship. If a PSO believes information reported by a provider is insufficient, a PSO is free to request additional information from a provider or to indicate appropriate limitations to the conclusions or analyses based on insufficient or incomplete information.

We seek public comment on two additional aspects regarding the timing of the obligation of a provider to report to a PSO in order for information to become protected patient safety work product and for the confidentiality protections to attach. The first issue relates to the timing between assembly or development of information for reporting and actual reporting under the proposed definition of patient safety work product. As currently proposed, information assembled or developed by a provider is not protected until the moment it is reported, (i.e., transmitted or transferred to a PSO). We are considering whether there is a need for a short period of protection for information assembled but not yet reported. We note that in such situations, a provider creates and operates a patient safety evaluation system. (See discussion of the definition of patient safety evaluation system at proposed § 3.20.) We further note that even without such short period of

protection, information assembled or developed by a provider but not yet reported may be subject to other protections in the proposed rule (e.g., see section 921(7)(A)(ii) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(A)(ii)).

Our intent is not to relieve the provider of the statutory requirement for reporting pursuant to section 921(7)(A)(i) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(A)(i), but to extend to providers flexibility to efficiently transmit or transfer information to a PSO for protection. A short period of protection for information assembled but not yet reported could result in greater operational efficiency for a provider by allowing information to be compiled and reported to a PSO in batches. It could also alleviate the uncertainty regarding the status of information that is assembled, but not yet reported for administrative reasons. If we do address this issue in the final rule, we seek input on the appropriate time period for such protection and whether a provider must demonstrate an intent to report in order to obtain protections. If we do not address this issue in the final rule, such information held by a provider would not be confidential until it is actually transmitted to a PSO under this prong of the definition of patient safety work product.

Second, for information to become patient safety work product under this prong of the definition, it must be assembled or developed for the purpose of reporting to a PSO and actually reported. We solicit comment on the point in time at which it can be established that information is being collected for the purpose of reporting to a PSO such that it is not excluded from the definition of patient safety work product as a consequence of it being collected, maintained or developed separately from a patient safety evaluation system. See section 921(7)(B)(ii) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(B)(ii). To assemble information with the purpose of reporting to a PSO, a PSO must potentially exist, and thus, we believe that collection efforts cannot predate the passage of the Patient Safety Act on July 29, 2005.

Information that is developed by a PSO for the conduct of patient safety activities. By law and as set forth in our proposal, information that is developed by a PSO for patient safety activities is patient safety work product. Section 921(7)(A)(i)(II) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(A)(i)(II). This section of the definition does not address information discussed in the previous section that is assembled or developed by a provider and is reported to a PSO which becomes patient safety work product under that section. Rather, this section addresses other information that a PSO collects for development from third parties, non-providers and other PSOs for patient safety activities.

For example, a PSO may be asked to assist a provider in analyzing a complex adverse event that took place. The initial information from the provider is protected because it was reported. If the PSO determines that the information is insufficient and conducts interviews with affected patients or collects additional data, that information is an example of the type of information that would be protected under this section of the definition. Even if the PSO ultimately decided not to analyze such information, the fact that the PSO collected and evaluated the information is a form of ''development'' transforming the information into patient safety work product. Such patient safety work product would be subject to confidentiality protections, and thus, the PSO would need safe disposal methods for any such information in accordance with its confidentiality obligations.

Information that constitutes the deliberations or analysis of, or identifies the fact of reporting pursuant to, a patient safety evaluation system. By law and as set forth in our proposal, information that constitutes the deliberations or analysis of, or identifies the fact of reporting pursuant to, a patient safety evaluation system is patient safety work product. Section 921(7)(A)(ii) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(A)(ii). This provision extends patient safety work product protections to any information that would identify the fact of reporting pursuant to a patient safety evaluation system or that constitutes the deliberations or analyses that take place within such a system. The fact of reporting through a patient safety evaluation system (e.g., a fax cover sheet, an e-mail transmitting data, and an oral transmission of information to a PSO) is patient safety work product.

With regard to providers, deliberations and analyses are protected while they are occurring provided they are done within a patient safety evaluation system. We are proposing that under paragraph (1)(ii) of this definition, any ''deliberations or analysis'' performed within the patient safety evaluation system becomes patient safety work product. In other words, to determine whether protections apply, the primary question is whether a patient safety evaluation system, which by law and as set forth in this proposed rule, is the collection, management, or analysis of information for reporting to a PSO, was in existence at the time of the deliberations and analysis.

To determine whether a provider had a patient safety evaluation system at the time that the deliberations or analysis took place, we propose to consider whether a provider had certain indicia of a patient safety evaluation system, such as the following: (1) The provider has a contract with a PSO for the receipt and review of patient safety work product that is in effect at the time of the deliberations and analysis; (2) the provider has documentation for a patient safety evaluation system demonstrating the capacity to report to a PSO at the time of the deliberations and analysis; (3) the provider had reported information to the PSO either under paragraph (1)(i)(A) of the proposed definition of patient safety work product or with respect to deliberations and analysis; or (4) the provider has actually reported the underlying information that was the basis of the deliberations or analysis to a PSO. For example, if a provider claimed protection for information as the deliberation of a patient safety evaluation system, and had a contract with the PSO at the time the deliberations took place, it would be reasonable to believe that the deliberations and analysis were related to the provider's PSO reporting activities. This is not an exclusive list. We note therefore that a provider may still be able to show that information was patient safety work product using other indications.

We note that the statutory protections for deliberations and analysis in a patient safety evaluation system apply without regard to the status of the underlying information being considered (i.e., it does not matter whether the underlying information being considered is patient safety work product or not). A provider can fully protect internal deliberations in its patient safety evaluation system over whether to report information to a PSO. The deliberations and analysis are protected, whether the provider chooses to report the underlying information to a PSO or not. However, the underlying information, separate and apart from the analysis or deliberation, becomes protected only when reported to a PSO. See section 921(7)(A)(i)(1) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(A)(i)(1).

To illustrate, consider a hospital that is reviewing a list of all near-misses

reported within the past 30 days. The purpose of the hospital's review is to analyze whether to report any or part of the list to a PSO. The analyses (or any deliberations the provider undertakes) are fully protected whether the provider reports any near-misses or not. The status of the near-misses list does not change because the deliberations took place. The fact that the provider deliberated over reporting the list does not constitute reporting and does not change the protected status of the list. Separate and apart from the analysis, this list of near misses is not protected unless it is reported. By contrast, this provision fully protects the provider's deliberations and analyses in its patient safety evaluation system regarding the list.

Delisting. In the event that a PSO is delisted for cause under proposed § 3.108(b)(1), a provider may continue to report to that PSO for 30 days after the delisting and the reported information will be patient safety work product. Section 924(f)(1) of the Public Health Service Act, 42 U.S.C. 299b–24(f)(1). Information reported to a delisted PSO after the 30-day period will not be patient safety work product. However, after a PSO is delisted, the delisted entity may not continue to generate patient safety work product by developing information for the conduct of patient safety activities or through deliberations and analysis of information. Any patient safety work product held or generated by a PSO prior to its delisting remains protected even after the PSO is delisted. See discussion in the preamble regarding proposed § 3.108(b)(2) for more information.

We note that proposed § 3.108(c) outlines the process for delisting based upon an entity's voluntary relinquishment of its PSO listing. As we discuss in the accompanying preamble, we tentatively conclude that the statutory provision for a 30-day period of continued protection does not apply after delisting due to voluntary relinquishment.

Even though a PSO may not generate new patient safety work product after delisting, it may still have in its possession patient safety work product, which it must keep confidential. The statute establishes requirements, incorporated in proposed § 3.108(b)(2) and (b)(3), that a PSO delisted for cause must meet regarding notification of providers and disposition of patient safety work product. We propose in § 3.108(c) to implement similar notification and disposition measures for a PSO that voluntarily relinquishes its listing. For further discussion of the obligations of a delisted PSO, see proposed § 3.108(b)(2), (b)(3), and (c).

What is not patient safety work product. By law, and as set forth in this proposed rule, patient safety work product does not include a patient's original medical record, billing and discharge information, or any other original patient or provider record; nor does it include information that is collected, maintained, or developed separately or exists separately from, a patient safety evaluation system. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered patient safety work product.

The specific examples cited in the Patient Safety Act of what is not patient safety work product—the patient's original medical record, billing and discharge information, or any other original patient record—are illustrative of the types of information that providers routinely assemble, develop, or maintain for purposes and obligations other than those of the Patient Safety Act. The Patient Safety Act also states that information that is collected, maintained, or developed separately, or exists separately from a patient safety evaluation system, is not patient safety work product. Therefore, if records are collected, maintained, or developed for a purpose other than for reporting to a PSO, those records cannot be patient safety work product. However, if, for example, a copy of such record is made for reporting to a PSO, the copy and the fact of reporting become patient safety work product. Thus, a provider could collect incident reports for internal quality assurance purposes, and later, determine that one incident report is relevant to a broader patient safety activity. If the provider then reports a copy of the incident report to a PSO, the copy of the incident report received by the PSO is protected as is the copy of the incident report as reported to the PSO that is maintained by the provider, while the original incident report collected for internal quality assurance purposes is not protected.

The proposed rule sets forth the statutory rule of construction that prohibits construing anything in this Part from limiting (1) the discovery of or admissibility of information that is not patient safety work product in a criminal, civil, or administrative proceeding; (2) the reporting of information that is not patient safety work product to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or (3) a provider's recordkeeping obligation with respect to information that is not patient safety work product under Federal, State or local law. Section 921(7)(B)(iii) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(B)(iii). Even when laws or regulations require the reporting of the information regarding the type of events also reported to PSOs, the Patient Safety Act does not shield providers from their obligation to comply with such requirements.

As the Patient Safety Act states more than once, these external obligations must be met with information that is not patient safety work product, and, in accordance with the confidentiality provisions, patient safety work product cannot be disclosed for these purposes. We note that the Patient Safety Act clarifies that nothing in this Part prohibits any person from conducting additional analyses for any purpose regardless of whether such additional analysis involves issues identical to or similar to those for which information was reported to or assessed by a PSO or a patient safety evaluation system. Section 922(h) of the Public Health Service Act, 42 U.S.C. 299b–22(h). A copy of information generated for such purposes may be entered into the provider's patient safety evaluation system for patient safety purposes although the originals of the information generated to meet external obligations do not become patient safety work product.

Thus, information that is collected to comply with external obligations is not patient safety work product. Such activities may include: State incident reporting requirements; adverse drug event information reporting to the Food and Drug Administration (FDA); certification or licensing records for compliance with health oversight agency requirements; reporting to the National Practitioner Data Bank of physician disciplinary actions; or complying with required disclosures by particular providers or suppliers pursuant to Medicare's conditions of participation or conditions of coverage. In addition, the proposed rule does not change the law with respect to an employee's ability to file a complaint with Federal or State authorities regarding quality of care, or with respect to any prohibition on a provider's threatening or carrying out retaliation against an individual for doing so; the filing of any such complaint would not be deemed to be a violation of the Patient Safety Act, unless patient safety work product was improperly disclosed in such filing.

Health Care Oversight Reporting and Patient Safety Work Product. The Patient Safety Act establishes a

protected space or system of protected information in order to allow frank discussion about causes and remediation of threats to patient safety. As described above, this protected system is separate, distinct, and resides alongside but does not replace other information collection activities mandated by laws, regulations, and accrediting and licensing requirements as well as voluntary reporting activities that occur for the purpose of maintaining accountability in the health care system. Information collection activities performed by the provider for purposes other than for reporting to a PSO by itself do not create patient safety work product. In anticipation of questions about how mandatory and voluntary reporting will continue to be possible, a brief explanation may be helpful regarding how this new patient safety framework would operate in relation to health care oversight activities (e.g., public health reporting, corrective actions, etc.).

Situations may occur when the original (whether print or electronic) of information that is not patient safety work product is needed for a disclosure outside of the entity but cannot be located while a copy of the needed information resides in the patient safety evaluation system. If the reason for which the original information is being sought does not align with one of the permissible disclosures, discussed in proposed Subpart C, the protected copy may not be released. Nevertheless, this does not preclude efforts to reconstruct the information outside of the patient safety evaluation system from information that is not patient safety work product. Those who participated in the collection, development, analysis, or review of the missing information or have knowledge of its contents can fully disclose what they know or reconstruct an analysis outside of the patient safety evaluation system.

The issue of how effectively a provider has instituted corrective action following identification of a threat to the quality or safety of patient care might lead to requests for information from external authorities. The Patient Safety Act does not relieve a provider of its responsibility to respond to such requests for information or to undertake or provide to external authorities evaluations of the effectiveness of corrective action, but the provider must respond with information that is not patient safety work product.

To illustrate the distinction, consider the following example. We would expect that a provider's patient safety evaluation system or a PSO with which the provider works may make recommendations from time to time to the provider for changes it should make in the way it manages and delivers health care. The list of recommendations for changes, whether they originate from the provider's patient safety evaluation system or the PSO with which it is working, are always patient safety work product. We would also note that not all of these recommendations will address corrective actions (i.e., correcting a process, policy, or situation that poses a threat to patients). It is also possible that a provider with an exemplary quality and safety record is seeking advice on how to perform even better. Whatever the case, the feedback from the provider's patient safety evaluation system or PSO may not be disclosed to external authorities unless permitted by the disclosures specified in Subpart C of this proposed rule.

The provider may choose to reject the recommendations it receives or implement some or all of the proposed changes. While the recommendations always remain protected, whether they are adopted or rejected by a provider, the actual changes that the provider implements to improve how it manages or delivers health care services (including changes in its organizational management or its care environments, structures, and processes) are not patient safety work product. In a practical sense, it would be virtually impossible to keep such changes confidential in any event, and we stress that if there is any distinction between the change that was adopted and the recommendation that the provider received, the provider can only describe the change that was implemented. The recommendation remains protected. Thus, if external authorities request a list of corrective actions that a provider has implemented, the provider has no basis for refusing the request. Even though the actions are based on protected information, the corrective actions themselves are not patient safety work product. On the other hand, if an external authority asks for a list of the recommendations that the provider did not implement or whether and how any implemented change differed from the recommendation the provider received, the provider must refuse the request; the recommendations themselves remain protected.

Person would mean a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private. We propose to define ''person'' because the Patient Safety Act requires that civil money penalties be imposed against ''person[s]'' that violate the confidentiality provisions. However, the Patient Safety Act does not provide a definition of ''person''. The Definition Act at 1 U.S.C. 1 provides, ''in determining any Act of Congress, *unless the context indicates otherwise* * * * the words 'person' and 'whoever' include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals'' (emphasis added). The Patient Safety Act indicates that States and other government entities may hold patient safety work product with the protections and liabilities attached, which is an expansion of the Definition Act provision. For this reason, we propose the broader definition of the term ''person''. We note that this proposed approach is consistent with the HHS Office of Inspector General (OIG) regulations, 42 CFR 1003.101, and the HIPAA Enforcement Rule, 45 CFR 160.103.

Provider would mean any individual or entity licensed or otherwise authorized under State law to provide health care services. The list of specific providers in the proposed rule includes the following: institutional providers, such as a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office (including a group practice), long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or individual clinicians, such as a physician, physician assistant, registered nurse, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner. This list is merely illustrative; an individual or entity that is not listed here but meets the test of state licensure or authorization to provide health care services is a provider for the purpose of this proposed rule.

The statute also authorizes the Secretary to expand the definition of providers. Under this authority, we propose to add the following to this list of providers:

(a) Agencies, organizations, and individuals within Federal, State, local, or Tribal governments that deliver health care, organizations engaged as contractors by the Federal, State, local or Tribal governments to deliver health care, and individual health care

practitioners employed or engaged as contractors by the Federal government to deliver health care. It appears that all of these agencies, organizations, and individuals could participate in, and could benefit from, working with a PSO.

(b) A corporate parent organization for one or more entities licensed or otherwise authorized to provide health care services under state law. Without this addition, hospital or other provider systems that are controlled by a parent organization that is not recognized as a provider under State law might be precluded from entering into system-wide contracts with PSOs. This addition furthers the goals of the statute to encourage aggregation of patient safety data and a coordinated approach for assessing and improving patient safety. We particularly seek comments regarding any concerns or operational issues that might result from this addition, and note that a PSO entering one system-wide contract still needs to meet the two contract minimum requirement based on section 924(b)(1)(C) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(1)(C), and set out and discussed in proposed § 3.102(b). The PSO can do this by entering into two contracts with different providers within the system.

(c) A Federal, State, local, or Tribal government unit that manages or controls one or more health care providers described in the definition of provider at (1)(i) and (2). We propose this addition to the definition of ''provider'' for the same reason that we proposed the addition of parent organization that has a controlling interest in one or more entities licensed or otherwise authorized to provide health care services under state law.

Research would have the same meaning as that term is defined in the HIPAA Privacy Rule at 45 CFR 164.501. In the HIPAA Privacy Rule, research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This definition is used to describe the scope of the confidentiality exception at proposed § 3.206(b)(6). We propose to use the same definition as in the HIPAA Privacy Rule to improve the level of coordination and to reduce the burden of compliance. At the same time, if there is a modification to the definition in the HIPAA Privacy Rule, the definition herein will automatically change with such regulatory action.

Respondent would mean a provider, PSO, or responsible person who is the subject of a complaint or a compliance review.

Responsible person would mean a person, other than a provider or PSO, who has possession or custody of identifiable patient safety work product and is subject to the confidentiality provisions. We note that because the Patient Safety Act has continued confidentiality protection at 42 U.S.C. 299b–22(d), many entities other than providers and PSOs may be subject to the confidentiality provisions. Thus, for example, researchers or law enforcement officials who obtain patient safety work product under one of the exceptions to confidentiality would be considered a ''responsible person''.

Workforce would mean employees, volunteers, trainees, contractors, and other persons whose conduct, in the performance of work for a provider, PSO or responsible person, is under the direct control of such provider, PSO or responsible person, whether or not they are paid by the provider, PSO or responsible person. We use the term workforce member in several contexts in the proposed rule. Importantly, in proposed § 3.402 where we discuss principal liability, we propose that an agent for which a principal may be liable can be a workforce member. We have included the term ''contractors'' in the definition of workforce member to clarify that such permitted sharing may occur with contractors who are under the direct control of the provider, PSO, or responsible person. For example, a patient safety activity disclosure by a provider to a PSO may be made directly to the PSO or to a consultant, as a workforce member, contracted by the PSO to help it carry out patient safety activities.

B. Subpart B—PSO Requirements and Agency Procedures

Proposed Subpart (B) sets forth requirements for Patient Safety Organizations (PSOs). This proposed Subpart specifies the certification and notification requirements that PSOs must meet, the actions that the Secretary may and will take relating to PSOs, the requirements that PSOs must meet for the security of patient safety work product, the processes governing correction of PSO deficiencies, revocation, and voluntary relinquishment, and related administrative authorities and implementation responsibilities. The requirements of this proposed Subpart would apply to PSOs, their workforce, a PSO's contractors when they hold patient safety work product, and the Secretary.

This proposed Subpart is intended to provide the foundation for new, voluntary opportunities to improve the safety, quality, and outcomes of patient care. The Patient Safety Act does not require a provider to contract with a PSO, and the proposed rule does not include such a requirement. However, we expect that most providers will enter into contracts with PSOs when seeking the confidentiality and privilege protections of the statute. Contracts offer providers greater certainty that a provider's claim to these statutory protections will be sustained, if challenged. For example, the statutory definition of patient safety work product describes the nature and purpose of information that can be protected, the circumstances under which deliberations or analyses are protected, and the requirement that certain information be reported to a PSO. Pursuant to a contractual arrangement, providers can require and receive assistance from PSOs to ensure that these requirements are fully met. Contracts can provide clear evidence that a provider is taking all reasonable measures to operate under the ambit of the statute in collecting, developing, and maintaining patient safety work product. Contracts enable providers to specify even stronger confidentiality protections in how they report information to a PSO or how the PSO handles and uses the information.

Contracts can also give providers greater assurance that they will have access to the expertise of the PSO to provide feedback regarding their patient safety events. While some providers may have patient safety expertise in-house, a PSO has the potential to offer providers considerable additional insight as a result of its expertise and ability to aggregate and analyze data from multiple providers and multiple PSOs. Experience has demonstrated that such aggregation and analysis of large volumes of data, such as a PSO has the ability to do, will often yield insights into the underlying causes of the hazards and risks associated with patient care that are simply not apparent when these analyses are limited to the information available from only one office, clinic, facility, or system.

Pursuant to a contract with a PSO, a provider may also be able to obtain from a PSO operational guidance or best practices with respect to operation of a patient safety evaluation system. Such a contract also provides a mechanism for a provider to control the nature and extent of a PSO's aggregation of its data with those of other providers or PSOs, and the nature of related analysis and discussion of such data. A provider can also require, pursuant to its contract with a PSO, that the PSO will notify the provider if improper disclosures are

made of patient safety work product relating to that provider.

This proposed Subpart enables a broad variety of health care providers to work voluntarily with entities that have certified to the Secretary that they have the ability and expertise to carry out broadly defined patient safety activities of the Patient Safety Act and, therefore, to serve as consultants to eligible providers to improve patient care. In accordance with the Patient Safety Act, we propose an attestation-based process for initial and continued listing of an entity as a PSO. This includes an attestation-based approach for meeting the statutory requirement that each PSO, within 24 months of being listed and in each sequential 24-month period thereafter, must have bona fide contracts with more than one provider for the receipt and review of patient safety work product.

This streamlined approach of the statute and the proposed rule is intended to encourage the rapid development of expertise in health care improvement. This framework allows the marketplace to be the principal arbiter of the capabilities of each PSO. Listing as a PSO by the Secretary does not entitle an entity to Federal funding. The financial viability of most PSOs will derive from their ability to attract and retain contracts with providers or to attract financial support from other organizations, such as charitable foundations dedicated to health system improvement. Even when a provider organization considers establishing a PSO (what this proposed rule terms a component PSO) to serve the needs of its organization, we expect it will weigh the value of, and the business case for, such a PSO.

Proposed Subpart B attempts to minimize regulatory burden while fostering transparency to enhance the ability of providers to assess the strengths and weaknesses of their choice of PSOs. For example, we encourage, but do not require, an entity seeking listing to develop and post on their own Web sites narrative statements describing the expertise of the personnel the entity will have at its disposal, and outlining the way it will approach its mission and comply with the statute's certification requirements.

We similarly propose to apply transparency to our implementation of the statute's requirement for disclosure by PSOs of potential conflicts of interest with their provider clients. While the statute only requires public release of the findings of the Secretary after review of such disclosures, we propose to make public, consistent with applicable law, including the Freedom of Information Act, a PSO's disclosure statements as well. In our view, in addition to having the benefit of the Secretary's determination, a provider, as the prospective consumer of PSO services, should be able to make its own determination regarding the appropriateness of the relationships that a PSO has with its other provider clients and the impact those relationships might have on its particular needs. For example, a provider might care if a PSO—despite the Secretary's determination that it had been established with sufficient operational and other independence to qualify for listing as a PSO—was owned, operated, or managed by the provider's major competitor.

The provisions of this proposed Subpart also emphasize the need for vigilance in providing security for patient safety work product. To achieve the widespread provider participation intended by this statute, PSOs must foster and maintain the confidence of providers in the security of patient safety work product in which providers and patients are identified. Therefore, we propose to require a security framework, which each PSO must address with standards it determines appropriate to the size and complexity of its organization, pertaining to the separation of data and systems and to security management control, monitoring, and assessment.

The Patient Safety Act recognizes that PSOs will need to enter business associate agreements to receive protected health information from providers that are covered entities under the HIPAA Privacy Rule. As a business associate of such a provider, a PSO will have to meet certain contractual requirements on the use and disclosure of protected health information for compliance with the HIPAA Privacy Rule that are in addition to the requirements set forth in this proposed rule. Those requirements include the notification of a covered entity when protected health information is inappropriately disclosed in violation of the HIPAA Privacy Rule.

We do not propose to require reporting of impermissible disclosures of other patient safety work product that does not contain protected health information. We solicit comments on whether to parallel the business associate requirements of the HIPAA Privacy Rule. Such a requirement, if implemented, would require a PSO to notify the organizational source of patient safety work product if the information it shared has been impermissibly used or disclosed. Note that such reporting requirements could be voluntarily agreed to by contract between providers and their PSO.

Section 924(b)(2)(A) and (B) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(2)(A) and (B), suggests Congressional concern that a strong firewall must be maintained between a component PSO and the rest of the organization(s) of which it is a part. This proposed subpart proposes specific safeguards that such component PSOs must implement to effectively address those concerns.

As this discussion suggests, in developing this proposed Subpart, we have proposed the most specific requirements in the areas of security and disclosure of potential conflicts of interest. We expect to offer technical assistance and encourage transparency wherever possible to promote implementation, compliance, and correction of deficiencies. At the same time, this proposed Subpart establishes processes that will permit the Secretary promptly to revoke a PSO's certification and remove it from listing, if such action proves necessary.

1. Proposed § 3.102—Process and Requirements for Initial and Continued Listing of PSOs

Proposed § 3.102 sets out: The submissions that the Department, in carrying out its responsibilities, proposes to require, consistent with the Patient Safety Act, for initial and continued listing as a PSO; the certifications that all entities must make as part of the listing process; the additional certifications that component organizations must make as part of the listing process; the requirement for biennial submission of a certification that the PSO has entered into the required number of contracts; and the circumstances under which a PSO must submit a disclosure statement regarding the relationships it has with its contracting providers.

(A) Proposed § 3.102(a)—Eligibility and Process for Initial and Continued Listing

In this section, we propose to establish a streamlined certification process that minimizes barriers to entry for a broad variety of entities seeking to be listed as a PSO. With several exceptions, any entity—public or private, for-profit or not-for profit—may seek initial or continued listing by the Secretary as a PSO. The statute precludes a health insurance issuer and a component of a health insurance issuer from becoming a PSO (section 924(b)(1)(D) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(1)(D)).

In addition, we propose to preclude any other entity, public or private, from

seeking listing as a PSO if the entity conducts regulatory oversight of health care providers, including accreditation or licensure. We propose this restriction for consistency with the statute, which seeks to foster a ''culture of safety'' in which health care providers are confident that the patient safety events that they report will be used for learning and improvement, not oversight, penalties, or punishment. Listing organizations with regulatory authority as PSOs would be likely to undermine provider confidence that adequate separation of PSO and regulatory activities would be maintained.

We note that the Patient Safety Act permits a component organization of an entity to seek listing as a PSO if the component organization establishes a strong firewall between its activities as a PSO and the rest of the organization(s) of which it is a part. As drafted, this proposed regulation permits a component organization of an entity with any degree of regulatory authority to seek listing as a component PSO. We have not proposed any restrictions on such component organizations for several reasons. First, we expect that the statutory requirement for a strong firewall between a component PSO and its parent organization(s) with respect to its activities as a PSO and the protected information it holds will provide adequate safeguards. Second, providers will have access to the names of parent organizations of component PSOs. We propose in § 3.102(c) that any component organization must disclose the name of its parent organization(s) (see the proposed definitions of component and parent organizations in § 3.20). We intend to make this information publicly available and expect to post it on the PSO Web site we plan to establish (see the preamble discussion regarding proposed § 3.104(d)). This will provide transparency and enable providers to determine whether the organizational affiliation(s) of a component PSO are of concern. Finally, we believe that allowing the marketplace to determine whether a component PSO has acceptable or unacceptable ties to an entity with regulatory authority is consistent with our overall approach to regulation of PSOs.

At the same time, we recognize that some organizations exercise a considerable level of regulatory oversight over providers and there may be concerns that such organizations could circumvent the firewalls proposed below in § 3.102(c) or might attempt to require providers to work with a component PSO that the regulatory entity creates. Accordingly, we specifically seek comment on the approach we have proposed and whether we should consider a broader restriction on component organizations of entities that are regulatory. For example, should components of state health departments be precluded from seeking listing because of the broad authority of such departments to regulate provider behavior? If a broader restriction is proposed, we would especially welcome suggestions on clear, unambiguous criteria for its implementation.

We will develop certification forms for entities seeking initial and continued listing that contain or restate the respective certifications described in proposed § 3.102(b) and § 3.102(c). An individual with authority to make commitments on behalf of the entity seeking listing would be required to acknowledge each of the certification requirements, attest that the entity meets each of the certification requirements on the form, and provide contact information for the entity. The certification form would also require an attestation that the entity is not subject to the limitation on listing proposed in this subsection and an attestation that, once listed as a PSO, it will notify the Secretary if it is no longer able to meet the requirements of proposed § 3.102(b) and § 3.102(c).

To facilitate the development of a marketplace for the services of PSOs, entities are encouraged, but not required, to develop and post on their own Web sites narratives that specify how the entity will approach its mission, how it will comply with the certification requirements, and describe the qualifications of the entity's personnel. With appropriate disclaimers of any implied endorsement, we expect to post citations or links to the Web sites of all listed entities on the PSO Web site that we plan to establish pursuant to proposed § 3.104(d). We believe that clear narratives of how PSOs will meet their statutory and regulatory responsibilities will help providers, who are seeking the services of a PSO, to assess their options. The Department's PSO Web site address will be identified in the final rule and will be available from AHRQ upon request.

(B) Proposed § 3.102(b)—Fifteen General Certification Requirements

In accordance with section 924(a) of the Public Health Service Act, 42 U.S.C. 299b–24(a), the proposed rule would require all entities seeking initial or continued listing as a PSO to meet 15 general certification requirements: eight requirements related to patient safety activities and seven criteria governing their operation. At initial listing, the entity would be required to certify that it has policies and procedures in place to carry out the eight patient safety activities defined in the Patient Safety Act and incorporated in proposed § 3.20, and upon listing, would meet the seven criteria specified in proposed § 3.102 (b)(2). Submissions for continued listing would require certifications that the PSO is performing, and will continue to perform, the eight patient safety activities and is complying with, and would continue to comply with, the seven criteria.

(1) Proposed § 3.102(b)(1)—Required Certification Regarding Eight Patient Safety Activities

Proposed § 3.102(b)(1) addresses the eight required patient safety activities that are listed in the definition of patient safety activities at proposed § 3.20 (section 921(5) of the Public Health Service Act, 42 U.S.C. 299b–21(5)). Because certification relies primarily upon attestations by entities seeking listing, rather than submission and review of documentation, it is critical that entities seeking listing have a common and shared understanding of what each certification requirement entails. We conclude that five of the eight required patient safety activities need no elaboration. These five patient safety activities include: Efforts to improve patient safety and quality; the collection and analysis of patient safety work product; the development and dissemination of information with respect to improving patient safety; the utilization of patient safety work product for the purposes of encouraging a culture of safety and providing feedback and assistance; and the utilization of qualified staff.

We address a sixth patient safety activity, related to the operation of a patient safety evaluation system, in the discussion of the definition of that term in proposed § 3.20. We provide greater clarity here regarding the actions that an entity must take to comply with the remaining two patient safety activities, which involve the preservation of confidentiality of patient safety work product and the provision of appropriate security measures for patient safety work product.

We interpret the certification to preserve confidentiality of patient safety work product to require conformance with the confidentiality provisions of proposed Subpart C as well as the requirements of the Patient Safety Act. Certification to provide appropriate security measures require PSOs, their workforce members, and their

contractors when they hold patient safety work product to conform to the requirements of proposed § 3.106, as well as the provisions of the Patient Safety Act.

(2) Proposed § 3.102(b)(2)—Required Certification Regarding Seven PSO Criteria

Proposed § 3.102(b)(2) lists seven criteria that are drawn from the Patient Safety Act (section 924(b) of the Public Health Service Act, 42 U.S.C. 299b–24(b)), which an entity must meet during its period of listing. We conclude that the statutory language for three of the seven required criteria is clear and further elaboration is not required. These three criteria include: The mission and primary activity of the entity is patient safety, the entity has appropriately qualified staff, and the entity utilizes patient safety work product for provision of direct feedback and assistance to providers to effectively minimize patient risk.

Two of the criteria are addressed elsewhere in the proposed rule: the exclusion of health insurance issuer or components of health insurance issuers from being PSOs is discussed above in the context of the definition of that term in proposed § 3.20 and the requirements for submitting disclosure statements are addressed in the preamble discussion below regarding proposed § 3.102(d)(2) (the proposed criteria against which the Secretary will review the disclosure statements are set forth in § 3.104(c)). The remaining two PSO criteria—the minimum contract requirement and the collection of data in a standardized manner—are discussed here.

The Minimum Contracts Requirement. First, we propose to clarify the requirement in section 924(b)(1)(C) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(1)(C) that a PSO must enter into bona fide contracts with more than one provider for the receipt and review of patient safety work product within every 24-month period after the PSO's initial date of listing.

We note that the statutory language establishes four conditions that must be met for a PSO to be in compliance with this requirement. We propose to interpret two of them for purposes of clarity in the final rule: (1) The PSO must have contracts with more than one provider, and (2) the contract period must be for ''a reasonable period of time.'' Most contracts will easily meet the third requirement: that contracts must be ''bona fide'' (our definition is in proposed § 3.20). Finally, the fourth requirement, that contracts must involve the receipt and review of patient safety work product, does not require elaboration.

We propose that a PSO would meet the requirement for ''contracts with more than one provider'' if it enters a minimum of two contracts within each 24-month period that begins with its initial date of listing. We note that the statutory requirement in section 924(b)(1)(C) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(1)(C), unambiguously requires multiple contracts (i.e., more than one). One contract with two or more providers would not fully meet the statute's requirement. To illustrate, one contract with a 50-hospital system would not meet the requirement; two 25-hospital contracts with that same hospital system would meet the requirement. We believe that the statutory requirement was intended to encourage PSOs to aggregate data from multiple providers, in order to expand the volume of their data, thereby improving the basis on which patterns of errors and the causes for those errors can be identified. This statutory objective is worth noting as a goal for PSOs. A PSO can achieve this goal by aggregating data from multiple providers or by pooling or comparing data with other PSOs, subject to statutory, regulatory, and contractual limitations.

The statute requires that these contracts must be ''for a reasonable period of time.'' We propose to clarify in the final rule when a PSO would be in compliance with this statutory requirement. The approach could be time-based (e.g., a specific number of months), task-based (e.g., the contract duration is linked to completion of specific tasks but, under this option, the final rule would not set a specific time period), or provide both options. We seek comments on the operational implications of these alternative approaches and the specific standard(s) for each option that we should consider. By establishing standard(s) in the final rule, we intend to create certainty for contracting providers and PSOs as to whether the duration requirement has been met. We note that whatever requirement is incorporated in the final rule will apply only to the two required contracts. A PSO can enter other contracts, whether time-based or task-based, without regard to the standard(s) for the two required contracts.

Apart from the requirements outlined above, there are no limits on the types of contracts that a PSO can enter; its contracts can address all or just one of the required patient safety activities, assist providers in addressing all, or just a specialized range, of patient safety topics, or the PSO can specialize in assisting specific types of providers, specialty societies, or provider membership organizations. Because of the limits on the extraterritorial application of U.S. law and the fact that privilege protections are limited to courts in the United States (Federal, State, etc.), the protections in the proposed rule apply only to protected data shared between PSOs and providers within the United States and its territories; there is only this one geographical limitation on a PSO's operations.

If they choose to do so, providers and PSOs may enter into contracts that specify stronger confidentiality protections than those specified in this proposed rule and the Patient Safety Act (section 922(g)(4) of the Public Health Service Act, 42 U.S.C. 299b–22 (g)(3)). For example, a provider could choose to de-identify or anonymize information it reports to a PSO.

We note that the Secretary proposes to exercise his authority to extend the definition of ''provider'' for the purposes of this statute to include a provider's ''parent organization'' (both terms are defined in proposed § 3.20). This proposed addition is intended to provide an option for health systems (e.g., holding companies or a state system) to enter system-wide contracts with PSOs if they choose to do so. This option would not be available in the absence of this provision because the parent organizations of many health care systems are often corporate management entities or governmental entities that are not considered licensed or authorized health care providers under state law.

Collecting data in a standardized manner. Section 924(b)(1)(F) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(1)(F), requires PSOs, to the extent practical and appropriate, to collect patient safety work product from providers in a standardized manner, to permit valid comparisons of similar cases among similar providers. One of the goals of the legislation is to facilitate a PSO aggregating sufficient data to identify and to address underlying causal factors of patient safety problems. A PSO is more valuable if it is able to aggregate patient safety work product it receives directly from multiple providers, and if it chooses to do so, aggregate its data with patient safety work product received from other PSOs and/or share nonidentifiable patient safety work product with a network of patient safety databases described in section 923 of the Public Health Service Act, 42 U.S.C. 299b–23. We recognize that if patient safety work product is not collected initially using common data

elements and consistent definitions, it may be difficult to aggregate such data subsequently in order to develop valid comparisons across providers and potentially, PSOs. We also recognize, however, that the providers who work with PSOs may have varying levels of sophistication with respect to patient safety issues and that reporting patient safety work product to a PSO in a standardized manner or using standardized reporting formats may not be initially practicable for certain providers or in certain circumstances. The discussion which follows outlines the timetable and the process to which we are committed.

The Secretary intends to provide ongoing guidance to PSOs on formats and definitions that would facilitate the ability of PSOs to aggregate patient safety work product. We expect to provide initial guidance beginning with the most common types of patient safety events, before the final rule is issued, to facilitate the ability of PSOs to develop valid comparisons among providers. The Department will make such formats and definitions available for public comment in a non-regulatory format via publication in the **Federal Register**. We are considering, and we seek comment on, including a clarification in the final rule, that compliance with this certification requirement would mean that a PSO, to the extent practical and appropriate, will aggregate patient safety work product consistent with the Secretary's guidance regarding reporting formats and definitions when such guidance becomes available.

The process for developing and maintaining common formats. AHRQ has established a process to develop common formats that: (1) Is evidence-based; (2) harmonizes across governmental health agencies; (3) incorporates feedback from the public, professional associations/organizations, and users; and (4) permits timely updating of these clinically-sensitive formats.

In anticipation of the need for common formats, AHRQ began the process of developing them in 2005. That process consists of the following steps: (1) Develop an inventory of functioning patient safety reporting systems to inform the construction of the common formats (an evidence base). Included in this inventory, now numbering 64 systems, are the major Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) reporting systems as well as many from the private sector. (2) Convene an interagency Patient Safety Work Group (PSWG) to develop draft formats. Included are major health agencies within the Department—CDC, Centers for Medicare and Medicaid Services, FDA, Health Resources and Services Administration, the Indian Health Service (IHS), the National Institutes of Health—as well as the Department of Defense (DoD) and the Veterans Administration (VA). (3) Pilot test draft formats—to be conducted in February–March of 2008 in DoD, IHS, and VA facilities. (4) Publish version 0.1 (beta) of the formats in the **Federal Register**, along with explanatory material, and solicit public comment—planned for July/August 2008. (5) Let a task order contract (completed) with the National Quality Forum (NQF) to solicit input from the private sector regarding the formats. NQF's role will be periodically to solicit input from the private sector to assist the Department in updating its versions of the formats. NQF will begin with version 0.1 (beta) of the common formats and solicit public comments (including from providers, professional organizations, the general public, and PSOs), triage them in terms of immediacy of importance, set priorities, and convene expert panel(s) to offer advice on updates to the formats. This process will be a continuing one, guiding periodic updates of the common formats. (6) Accept input from the NQF, revise the formats in consultation with the PSWG, and publish subsequent versions in the **Federal Register**. Comments will be accepted at all times from public and governmental sources, as well as the NQF, and used in updating of the formats.

This process ensures intergovernmental consistency as well as input from the private sector, including, most importantly, those who may use the common formats. This latter group, the users, will be the most sensitive to and aware of needed updates/improvements to the formats. The PSWG, acting as the fulcrum for original development and continuing upgrading/maintenance, assures consistency of definitions/formats among government agencies. For instance, the current draft formats follow CDC definitions of healthcare associated infections and FDA definitions of adverse drug events. AHRQ has been careful to promote consensus among Departmental agencies on all draft common formats developed to date. The NQF is a respected private sector organization that is suited to solicit and analyze input from the private sector.

We welcome comments on our proposed approach to meeting statutory objectives.

(C) Proposed § 3.102(c)—Additional Certifications Required of Component Organizations

Section 924(b)(2) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(2) and the proposed definition of component organization in proposed § 3.20 requires an entity that is a component of another organization or multi-organizational enterprise that seeks initial or continued listing to certify that it will meet three requirements in addition to certifying that it will meet the 15 general requirements specified in proposed § 3.102(b). We have indicated the types of entities that would be required to seek listing as a component organization in our discussion of the proposed definitions in proposed § 3.20 of the terms ''component organization'' and ''parent organization.'' To be listed as a component PSO, an entity would also be required to make three additional certifications regarding the entity's independent operation and separateness from the larger organization or enterprise of which it is a part: the entity would certify to (1) the secure maintenance of documents and information separate from the rest of the organization(s) or enterprise of which it is a part; (2) the avoidance of unauthorized disclosures to the organization(s) or enterprise of which it is a part; and (3) the absence of a conflict between its mission and the rest of the organization(s) or enterprise of which it is a part. We propose in § 3.102(c) specific requirements that will ensure that such component PSOs implement the type of safeguards for patient safety work product that the three additional statutory certification requirements for component organizations are intended to provide.

First, the statute requires a component PSO to maintain patient safety work product separate from the rest of the organization(s) or enterprise of which it is a part (section 924(b)(2)(A) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(2)(A)). To ensure compliance with this statutory requirement, we considered, but did not include here, a proposal to prohibit a component PSO from contracting, subcontracting, or entering any agreement with any part of the organization(s) or enterprise of which it is a part for the performance of any work involving the use of patient safety work product. We seek comment on the limited exception proposed in § 3.102(c) here that would permit such contracts or subcontracts only if they can be carried out in a manner that is consistent with the statutory

requirements of this section. This means that, while a component PSO could enter such arrangements involving the use of patient safety work product with a unit of the organization(s) or enterprise of which it is a part, the component PSO would maintain the patient safety work product and be responsible for its security (i.e., control the access and use of it by the contracting unit). In addition, under our proposal, while allowing access to the contracting unit of the identifiable patient safety work product necessary to carry out the contractual assignment would be a permissible disclosure, the component PSO would remain responsible for ensuring that the contracting unit does not violate the prohibitions related to unauthorized disclosures required under 924(b)(2)(B) of the PHS Act, 42 U.S.C. 299b–24(b)(2)(B), (i.e., disclosures to other units of the organization or enterprise) and that there is no conflict between the mission of the component PSO and the contracting unit, as required under 924(b)(2)(C) of the PHS Act, 42 U.S.C. 299b–24(b)(2)(C). We invite comment on whether such a limited exception is necessary or appropriate and, if so, the appropriateness of the restrictions we have proposed.

Second, a component PSO would not be permitted to have a shared information system with the rest of the organization(s) since this might provide unauthorized access to patient safety work product. For example, we intend to prohibit a component PSO from storing any patient safety work product in information systems or databases to which the rest of the organization(s) or enterprise of which it is a part would have access or the ability to remove or transmit a copy. We preliminarily conclude that most security measures, such as password protection of the component PSO's information, are too easily circumvented.

Third, the proposed rule provides that the workforce of the component PSO must not engage in work for the rest of the organization(s) if such work could be informed or influenced by the individual's knowledge of identifiable patient safety work product. For example, a component PSO could share accounting or administrative support staff under our proposal because the work of these individuals for the rest of the organization(s) would not be informed or influenced by their knowledge of patient safety work product. By contrast, if the rest of the organization provides health care services, a physician who served on a parent organization's credentialing, hiring, or disciplinary committee(s) could not also work for the PSO. Knowledge of confidential patient safety work product could influence his or her decisions regarding credentialing, hiring, or disciplining of providers who are identifiable in the patient safety work product.

We provide one exception to the last prohibition. It is not our intent to prohibit a clinician, whose work for the rest of the organization is solely the provision of patient care, from undertaking work for the component PSO. We see no conflict if the patient care provided by the clinician is informed by the clinical insights that result from his or her work for the component PSO. If a clinician has duties beyond patient care, this exception only applies if the other duties do not violate the general prohibition (i.e., that the other duties for the rest of the organization(s) cannot be informed by knowledge of patient safety work product).

As part of the requirement that the PSO must certify that there is no conflict between its mission and the rest of the organization(s), we propose that the certification form will require the PSO to provide the name(s) of the organization(s) or enterprise of which it is a part (see the discussions of our definitions of parent and component organizations in proposed § 3.20).

We have not proposed specific standards to determine whether conflicts exist between a PSO and other components of the organization or enterprise of which it is a part. We recognize that some industries and particular professions, such as the legal profession through state-based codes of professional responsibility, have specific standards or tests for determining whether a conflict exists. We request comments on whether the final rule should include any specific standards, and, if so, what criteria should be put in place to determine whether a conflict exists.

(D) Proposed § 3.102(d)—Required Notifications

Proposed § 3.102(d) establishes in regulation two required notifications that implement two statutory provisions: a notification to the Secretary certifying whether the PSO has met the biennial requirement for bona fide contracts with more than one provider (section 924(b)(1)(C) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(1)(C)); and the submission of a disclosure statement to the Secretary whenever a PSO has established specific types of relationships (discussed below) with a contracting provider, in particular where a PSO is not managed or controlled independently from, or if it does not operate independently from, a contracting provider (section 924(b)(1)(E) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(1)(E)).

(1) Proposed § 3.102(d)(1)—Notification Regarding PSO Compliance With the Minimum Contract Requirement

Proposed § 3.102(d)(1) requires a PSO to notify the Secretary whether it has entered at least two bona fide contracts that meet the requirements of proposed § 3.102(b)(2). The notification requirement implements the statutory requirement in section 924(b)(1)(C) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(1)(C), that a PSO must have contracts with more than one provider. Notification to the Secretary will be by attestation on a certification form developed pursuant to proposed § 3.112. Prompt notification of the Secretary that a PSO has entered two or more contracts will result in earlier publication of that information by the Secretary and this may be to the PSO's benefit.

We propose that the Secretary receive initial notification from a PSO no later than 45 calendar days before the last day of the period that is 24 months after the date of its initial listing and 45 calendar days prior to the last day of every 24-month period thereafter. While each PSO will have the full statutory period of 24 months to comply with this requirement, we propose an earlier date for notification of the Secretary to harmonize this notification requirement with the requirement, established by section 924(e) of the Public Health Service Act, 42 U.S.C. 299b–24(e), that the Secretary provide each PSO with a period of time to correct a deficiency. If the Secretary were to provide a period for correction that begins after the 24-month period has ended, the result would be that some PSOs would be granted compliance periods that extend beyond the unambiguous statutory deadline for compliance. To avoid this unfair result, we propose that a PSO certify to the Secretary whether it has complied with this requirement 45 calendar days in advance of the final day of its applicable 24-month period.

If a PSO notifies the Secretary that it cannot certify compliance or fails to submit the required notification, the Secretary, pursuant to proposed § 3.108(a)(2), will then issue a preliminary finding of deficiency and provide a period for correction that extends until midnight of the last day of the applicable 24-month assessment period for the PSO. In this way, the requirement for an opportunity for correction can be met without granting any PSO a period for compliance that

exceeds the statutory limit. We invite comments on alternative approaches to harmonize these two potentially conflicting requirements.

We note that contracts that are entered into after midnight on the last day of the applicable 24-month period do not count toward meeting the two-contract requirement for that 24-month assessment period. If a PSO does not meet the requirement by midnight of the last day of the applicable 24-month assessment period, the Secretary will issue a notice of revocation and delisting pursuant to proposed § 3.108(a)(3).

(2) Proposed § 3.102(d)(2)—Notification Regarding PSO's Relationships With Its Contracting Providers

Proposed § 3.102(d)(2) establishes the circumstances under which a PSO must submit a disclosure statement to the Secretary regarding its relationship(s) with any contracting provider(s) and the deadline for such required submissions.

The purpose of this disclosure requirement is illuminated by the statutory obligation of the Secretary, set forth in section 924(c)(3) of the Public Health Service Act, 42 U.S.C. 299b–24(c)(3), to review the disclosure statements and make public findings ''whether the entity can fairly and accurately perform the patient safety activities of a patient safety organization.'' To provide the Secretary with the information necessary to make such a judgment, section 924(b)(1)(E) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(1)(E), requires a PSO to fully disclose information to the Secretary if the PSO has certain types of relationships with a contracting provider and, if applicable, whether the PSO is not independently managed or controlled, or if it does not operate independently from, the contracting provider.

The statutory requirement for a PSO to submit a disclosure statement applies only when a PSO has entered into a contract with a provider; if there is no contractual relationship between the PSO and a provider pursuant to the Patient Safety Act, a disclosure statement is not required. Even when a PSO has entered a contract with a provider, we propose that a PSO would need to file a disclosure statement regarding a contracting provider only when the circumstances, specified in section 924(c)(3) of the Public Health Service Act, 42 U.S.C. 299–24(c)(3), and discussed here, are present.

A PSO is first required to assess whether a disclosure statement must be submitted to the Secretary when the PSO enters a contract with a provider, but we note that the disclosure requirement remains in effect during the entire contract period. Even when a disclosure statement is not required at the outset of the contract period, if the circumstances discussed here arise, a disclosure statement must be submitted at that time to the Secretary for review.

With respect to a provider with which it has entered a contract, a PSO is required to submit a disclosure statement to the Secretary only if either or both of the following circumstances are present. First, a disclosure statement must be filed if the PSO has any financial, reporting, or contractual relationships with a contracting provider (other than the contract entered into pursuant to the Patient Safety Act). Second, taking into account all relationships that the PSO has with that contracting provider, a PSO must file a disclosure statement if it is not independently managed or controlled, or if it does not operate independently from, the contracting provider.

With respect to financial, reporting or contractual relationships, the proposed rule states that contractual relationships that must be disclosed are not limited to formal contracts but encompass any oral or written arrangement that imposes responsibilities on the PSO. For example, the provider may already have a contract or other arrangement with the PSO for assistance in implementation of proven patient safety interventions and is now seeking additional help from the PSO for the review of patient safety work product. A financial relationship involves almost any direct or indirect ownership or investment relationship between the PSO and the contracting provider, shared or common financial interests, or direct or indirect compensation arrangement, whether in cash or in-kind. A reporting relationship includes a relationship that gives the provider access to information that the PSO holds that is not available to other contracting providers or control, directly or indirectly, over the work of the PSO that is not available to other contracting providers. If any such relationships are present, the PSO must file a disclosure statement and describe fully all of these relationships.

The other circumstance that triggers the requirement to disclose information to the Secretary is the provision of the Patient Safety Act that requires the entity to fully disclose ''if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity.'' See section 924(b)(1)(E) of the Public Health Service Act, 42 U.S.C. 299b–24(b)(1)(E). We propose to interpret this provision as noted above because we believe that the adverb ''independently'' modifies all three verbs—that is, that the entity is required to disclose when it is not managed independently from, is not controlled independently from, or is not operated independently from, any provider that contracts with the entity.

Disclosure would be required, for example, if the contracting provider created the PSO and exercises a degree of management or control over the PSO, such as overseeing the establishment of its budget or fees, hiring decisions, or staff assignments. Another example of such a relationship that would require disclosure would be the existence of any form of inter-locking governance structure. We recognize that contracts, by their very nature, will enable a contracting provider to specify tasks that the PSO undertakes or to direct the PSO to review specific cases and not others. These types of requirements reflect the nature of any contractual relationship and do not trigger a requirement to file such a disclosure statement. The focus of this provision as indicated in section 924(c)(3) of the Public Health Service Act, 42 U.S.C. 299b–24(c)(3), and here is on the exercise of the type of control that could compromise the ability of the PSO to fairly and accurately carry out patient safety activities. If the contracting provider exercises this type of influence over the PSO, the PSO must file a disclosure statement and fully disclose the nature of the influence exercised by the contracting provider.

To meet the statutory requirement for full disclosure, a PSO's submission should attempt to put the significance of the financial, reporting, or contractual relationship in perspective (e.g., relative to other sources of PSO revenue or other types of contractual or reporting relationships). We would also encourage PSOs to list any agreements, stipulations, or procedural safeguards that might offset the influence of the provider and that might protect the ability of the PSO to operate independently. By doing so, a PSO can ensure that its disclosure statements present a full and, if applicable, balanced picture of the relationships and degree of independence that exist between the PSO and its contracting provider(s).

We propose to require that, whenever a PSO determines that it must file a statement based upon these requirements, the Secretary must receive the disclosure statement within 45 calendar days. The PSO must make an initial determination on the date on which a contract is entered. If the PSO determines that it must file a disclosure

statement, the Secretary must receive the disclosure statement no later than 45 days after the date on which the contract was entered. During the contract period, the Secretary must receive a disclosure statement within 45 calendar days of the date on which either or both of the circumstances described above arise. If the Secretary determines, after the applicable 45-day period, that a required disclosure statement was not received from a PSO, the Secretary may issue to the PSO a notice of a preliminary finding of deficiency, the first step in the revocation process established by proposed § 3.108.

2. Proposed § 3.104—Secretarial Actions

Proposed § 3.104 describes the actions that the Secretary may and will take regarding certification submissions for listing or continued listing, the required notification certifying that the PSO has entered the required minimum of two contracts, and disclosure statements, including the criteria that the Secretary will use in reviewing such statements and the determinations the Secretary may make. This proposed section also outlines the types of information that the Secretary will make public regarding PSOs, specifies how, and for what period of time, the Secretary will list a PSO whose certification he has accepted and establishes an effective date for Secretarial actions under this proposed subpart. See section 924(c) of the Public Health Service Act, 42 U.S.C. 299b–24(c).

(A) Proposed § 3.104(a)—Actions in Response to Certification Submissions for Initial and Continued Listing as a PSO

Proposed § 3.104(a) describes the actions that the Secretary may and will take in response to certification for initial or continued listing as a PSO (section 924(c)(1)–(2) of the Public Health Service Act, 42 U.S.C. 299b–24(c)(1)–(2)), submitted to the Secretary pursuant to the requirements of proposed § 3.102. The decision on whether and how to list an entity as a PSO will be based upon a determination of whether the entity meets the applicable requirements of the Patient Safety Act and this proposed part. In most cases, it is anticipated that the Secretary will either accept the submission and list the entity or deny the listing on this basis.

In determining whether to list an entity as a PSO, the proposed rule requires the Secretary to consider the submitted certification and any relevant history, such as prior actions the Secretary has taken regarding the entity or PSO including delisting, any history of or current non-compliance by the entity or PSO with statutory or regulatory requirements or requests by the Secretary, relationships of the entity or PSO with providers and any findings by the Secretary in accordance with proposed § 3.104(c). Initially, the Secretary will rely solely on the submitted certification; entities seeking listing will not have any applicable history of the type specified for the Secretary to consider. Even over time, we anticipate that the Secretary would normally rely upon the submitted certification in making a listing determination.

There may be occasions in future years when the Secretary may need to take into account the history of an entity or PSO in making a determination for initial or continued listing. Examples of such situations might include: A PSO seeking continued listing that has a history of deficiencies; an entity seeking initial listing may be a renamed former PSO whose certifications had been revoked for cause by the Secretary; or the leadership of an entity seeking listing may have played a leadership role in a former PSO that failed to meet its obligations to providers during voluntary relinquishment (see proposed § 3.108(c)). In such circumstances, it may not be prudent for the Secretary to rely solely upon the certification submitted by the entity or PSO and this proposed subsection would enable the Secretary to seek additional information or assurances before reaching a determination on whether to list an entity. To ensure that the Secretary is aware of any relevant history before making a listing determination, without imposing additional burden on most entities seeking listing, we propose to include an attestation on the certification form that would require acknowledgement if the entity (under its current name or another) or any member of its workforce have been party to a delisting determination by the Secretary. We welcome comment on this proposal, or alternative approaches, for ensuring that the Secretary can carry out the requirements of this proposed section.

The Secretary also has the authority, under certain circumstances, to condition the listing of a PSO under section 924(c)(3) of the Public Health Service Act, 42 U.S.C. 299b–24(c)(3). The Secretary may establish conditions on the listing of a PSO following a determination, pursuant to proposed § 3.104(c), that such conditions are necessary to ensure that the PSO can fairly and accurately perform patient safety activities. A decision to impose such conditions will typically occur after the listing of a PSO, when the PSO submits a disclosure statement about its relationships with a contracting provider. It also could occur at the time of initial or continued listing based upon a Secretarial review of a disclosure statement submitted contemporaneously with the review of an entity's certification submission.

The Secretary expects to be able to conclude review of an application for initial or continued listing within 30 days of receipt unless additional information or assurances, as described above in the paragraph discussing the history of an entity or PSO, are required, or the application as initially submitted is incomplete. The Secretary will notify each entity that requests listing of the action taken on its certification submission for initial or continued listing. The Secretary will provide reasons when an entity's certification is not accepted and, if the listing is conditioned based upon a determination made pursuant to proposed § 3.104(c), the reasons for imposing conditions.

(B) Proposed § 3.104(b)—Actions Regarding PSO Compliance With the Minimum Contract Requirement

Proposed § 3.104(b) sets forth the required Secretarial action regarding PSO compliance with the requirement of the proposed rule for a minimum of two bona fide contracts. If a PSO attests, in the notification required by proposed § 3.102(d)(1), that it has met the requirement, the Secretary will acknowledge in writing receipt of the attestation and include information on the list established pursuant to proposed § 3.104(d) that the PSO has certified that it has met the requirement. If the PSO notifies the Secretary that it has not yet met the requirement, or if notification is not received from the PSO by the date required under proposed § 3.102(d)(1), the Secretary, pursuant to proposed § 3.108(a)(2), will issue a notice of a preliminary finding of deficiency to the PSO and provide an opportunity for correction that will extend no later than midnight of the last day of its applicable 24-month assessment period. Under this authority, the Secretary will require notification of correction and compliance from a PSO by midnight of the final day of the applicable 24-month period. If the deficiency has not been corrected by that date, the Secretary will issue promptly a notice of proposed revocation and delisting pursuant to the requirements of proposed § 3.108(a)(3).

(C) Proposed § 3.104(c)—Actions Regarding Required Disclosures by PSOs of Relationships With Contracting Providers.

Proposed § 3.104(c) establishes criteria that the Secretary will use to evaluate a disclosure statement submitted pursuant to proposed § 3.102(d)(2), specifies the determinations the Secretary may make based upon evaluation of any disclosure statement, and proposes public release, consistent with the Freedom of Information Act, of disclosure statements submitted by PSOs as well as the Secretary's findings (see section 924(c)(3) of the Public Health Service Act, 42 U.S.C. 299b–24(c)(3)).

In reviewing disclosure statements and making public findings, we propose that the Secretary consider the nature, significance, and duration of the relationship between the PSO and the contracting provider. We seek input on other appropriate factors to consider.

Following review of the disclosure statement, the Secretary will make public findings regarding the ability of the PSO to carry out fairly and accurately defined patient safety activities as required by the Patient Safety Act. The Secretary may conclude that the disclosures require no action on his part or, depending on whether the entity is listed or seeking listing, may condition his listing of the PSO, exercise his authority under proposed § 3.104(a) to refuse to list, or exercise his authority under proposed § 3.108 to revoke the listing of the entity. The Secretary will notify each entity of his findings and decision regarding each disclosure statement.

This subsection proposes to make this process transparent, recognizing that providers seeking to contract with a PSO may want to make their own judgments regarding the appropriateness of the disclosed relationships. Therefore, with the exception of information, such as information that would be exempt from disclosure under the Freedom of Information Act, we propose to make public each disclosure statement received from a PSO by including it on the list of PSOs maintained pursuant to proposed § 3.104(d) and we may post such statements on the PSO Web site we plan to establish. Public release of PSO disclosure statements would be in addition to the statutory requirement in section 924(c)(3) of the Public Health Service Act, 42 U.S.C. 299b–24(c)(3), that the Secretary's findings regarding disclosure statements must be made public. Greater transparency is intended to promote more informed decision making by providers, who are the primary customers for PSO services.

(D) Proposed § 3.104(d)—Maintaining a List of PSOs

Proposed § 3.104(d) implements the statutory requirement in section 924(d) of the Public Health Service Act, 42 U.S.C. 299b–24(d), that the Secretary compile and maintain a list of those entities whose PSO certifications have been accepted in accordance with proposed § 3.104(a) and which certifications have not been revoked or voluntarily relinquished in accordance with proposed § 3.108(b) or (c). The list will include contact information for each PSO, the effective date and time of listing of the PSO, a copy of each certification form and disclosure statement that the Secretary receives from the entity, and information on whether the PSO has certified that it has met the two contract requirement in each 24-month assessment period. The list will also include a copy of the Secretary's findings regarding any disclosure statements filed by each PSO, including whether any conditions have been placed on the listing of the entity as a PSO, and other information that this proposed subpart authorizes the Secretary to make public. To facilitate the development of a marketplace for the services of PSOs, we plan to establish a PSO Web site (or a future technological equivalent) and expect to post the list of PSOs on the PSO Web site, reserving the right to exclude information contained in disclosure statements that would be exempt from disclosure under the Freedom of Information Act. We seek comment on whether there are specific types of information that the Secretary should consider posting routinely on this Web site for the benefit of PSOs, providers, and other consumers of PSO services.

(E) Proposed § 3.104(e)—Three-Year Period of Listing

Proposed § 3.104(e) states that, when the Secretary has accepted certification submitted for initial or continued listing, the entity will be listed as a PSO for a period of three years (section 924(a)(2) of the Public Health Service Act, 42 U.S.C. 299b–24(a)(2)), unless the Secretary revokes the listing or the Secretary determines that the entity has voluntarily relinquished its status as a PSO (see proposed § 3.108).

This subsection also provides that the Secretary will send a written notice of imminent expiration to a PSO no later than 45 calendar days before the date on which the PSO's three-year period of listing expires if the Secretary has not received a certification seeking continued listing. This notice is intended to ensure that a PSO does not let its listing lapse inadvertently. We expect that the Secretary will include in the notice a date by which the PSO should submit its certifications to ensure that the Secretary has sufficient time to act before the current period of listing expires.

We are considering including in the final rule, and seek comment on, a requirement that the Secretary include information on the public list of PSOs maintained pursuant to § 3.104(d), that identifies the PSOs to which a notice of imminent expiration has been sent. The intent of such a requirement would be to ensure that a provider reporting data to such a PSO has adequate notice and time to ascertain, if it chooses to do so, whether that PSO intends to seek continued listing and, if not, to make alternative arrangements for reporting data to another PSO.

(F) Proposed § 3.104(f)—Effective Date of Secretarial Actions

Proposed § 3.104(f) states that, unless otherwise specified, the effective date of each action by the Secretary pursuant to this proposed subpart will be specified in the written notice that is sent to the entity. To ensure that an entity receives prompt notification, the Department anticipates sending such a notice by electronic mail or other electronic means in addition to a hard copy version. We are confident that any entity seeking listing as a PSO will have electronic mail capacity. For listing and delisting, the Secretary will specify both an effective time and date for such actions in the written notice. Our intent is to ensure clarity regarding when the entity can receive information that will be protected as patient safety work product.

3. Proposed § 3.106—Security Requirements

Proposed § 3.106 identifies the entities and individuals that are subject to the security requirements of this section and establishes the considerations that entities and individuals specified in subsection (a) should address to secure patient safety work product in their possession. This section provides a common framework for compliance with the requirement in section 921(5)(F) of the Public Health Service Act, 42 U.S.C. 299b–21(5)(F), that a PSO provide appropriate security measures with respect to patient safety work product. In light of the importance of data security to those who supply patient safety work product to any PSO, maintenance of data security will be a high and ongoing priority for PSOs.

(A) Proposed § 3.106(a)—Application

Proposed § 3.106(a) states that the security requirements in proposed § 3.106(b) apply to each PSO, its workforce members, and its contractors when the contractors hold patient safety work product. This proposed subsection applies the requirements at all times and at any location at which patient safety work product is held. We expect that it will be more efficient for most PSOs to contract for at least a portion of the expertise they need to carry out patient safety activities, including the evaluation of certain types of patient safety events. In such situations, when a PSO discloses patient safety work product to a contractor to assist the PSO in carrying out patient safety activities and the contractor maintains such patient safety work product at locations other than those controlled by the PSO, our intent is to ensure that these same security requirements apply. We recognize that some contractors that a PSO chooses to employ may not want to, or may not have the resources to, meet these requirements at other locations. In such circumstances, the contractors will need to perform their services at locations at which the PSO can ensure that these security requirements can be met.

We note that this regulation does not impose these requirements on providers, but agreements between PSOs and providers may by contract call for providers to adopt equivalent standards.

(B) Proposed § 3.106(b)—Security Framework

Proposed § 3.106(b) establishes a framework consisting of four categories for the security of patient safety work product that a PSO must consider, including security management, separation of systems, security control and monitoring, and security assessment.

This framework is consistent with the standards of the National Institute of Standards and Technology (NIST) that federal agencies must follow but this section does not impose on PSOs the specific NIST standards that Federal agencies must meet. We recognize that it is not likely that PSOs will have the scale of operation or the resources to comply with Federal data security standards. Instead, we propose to require that each PSO must consider the four categories of the NIST framework set forth in this section by developing appropriate and scalable standards that are suitable for the size and complexity of its organization. We seek comment on the extent to which this proposal adequately and appropriately identifies the most significant security issues, with respect to patient safety work product that PSOs receive, develop, or maintain, and which PSOs should be expected to address with due diligence, and the extent to which our approach provides PSOs with sufficient flexibility to develop scalable standards.

(1) Proposed § 3.106(b)(1)—Security Management

Proposed § 3.106(b)(1) requires the PSO to approach its security requirements by: documenting its security requirements for patient safety work product; taking steps to ensure that its workforce and contractors as specified in proposed § 3.106(a) understand their responsibilities regarding patient safety work product and the confidentiality requirements of the statute, including the potential imposition of civil money penalties for impermissible disclosures; and monitoring and improving the effectiveness of its security policies and procedures.

(2) Proposed § 3.106(b)(2)—Separation of Systems

Under the statute, to preserve the confidentiality of patient safety work product, it is important to maintain a clear separation between patient safety work product and information that is not protected, and a clear separation between patient safety activities and other activities. As a result, we have incorporated requirements in proposed § 3.106(b)(2) that PSOs must ensure such separation. The specific requirements for which a PSO must develop appropriate standards include: maintaining functional and physical separation of patient safety work product from other systems of records; protection of patient safety work product while it is held by the PSO; appropriate disposal or sanitization of media that have contained patient safety work product; and preventing physical access to patient safety work product by unauthorized users or recipients.

(3) Proposed § 3.106(b)(3)—Security Control and Monitoring

Proposed § 3.106(b)(3) requires that policies and procedures adopted by a PSO related to security control and monitoring must enable the PSO to identify and authenticate users of patient safety work product and must create an audit capacity to detect unlawful, unauthorized, or inappropriate activities involving access to patient safety work product. To ensure accountability, controls should be designed to preclude unauthorized removal, transmission or disclosures of patient safety work product.

(4) Proposed § 3.106(b)(4)—Security Assessment

Proposed § 3.106(b)(4) requires a PSO to develop policies and procedures that permit it to assess periodically the effectiveness and weaknesses of its overall approach to security of patient safety work product. A PSO needs to determine the frequency of security assessments, determine when it needs to undertake a risk assessment exercise so that the leadership and the workforce of the PSO are aware of the risks to PSO assets from security lapses, and specify how it will assess and adjust its procedures to ensure the security of its communications involving patient safety work product to and from providers and other authorized parties. Such communications are potentially vulnerable weak points for any security system and require ongoing special attention by a PSO.

4. Proposed § 3.108—Correction of Deficiencies, Revocation and Voluntary Relinquishment

Proposed § 3.108 describes the process by which PSOs will be given an opportunity to correct deficiencies, the process for revocation of acceptance of the certification submitted by an entity for cause and its removal from the list of PSOs, and specifies the circumstances under which an entity will be considered to have voluntarily relinquished its status as a PSO.

This section would establish procedural opportunities for a PSO to respond during the process that might lead to revocation. When the Secretary identifies a possible deficiency, the PSO would be given an opportunity to correct the record if it can demonstrate that the information regarding a deficiency is erroneous, and if the existence of a deficiency is uncontested, an opportunity to correct it. The PSO is encouraged to alert the Department if it faces unanticipated challenges in correcting the deficiency; we propose that the Secretary will consider such information in determining whether the PSO has acted in good faith, whether the deadline for corrective action should be extended, or whether the required corrective action should be modified. If the Secretary determines that the PSO has not timely corrected the deficiency and issues a notice of proposed revocation and delisting, the PSO will be given an automatic right of appeal to present its case in writing.

If the Secretary makes a decision to revoke acceptance of the entity's certification and remove it from the list

of PSOs, this proposed section specifies the required actions that the Secretary and the entity must take following such a decision. The proposed rule implements the statutory requirements for the establishment of a limited period during which providers can continue to report information to the former PSO and receive patient safety work product protections for these data, and establishes a framework for appropriate disposition of patient safety work product or data held by the former PSO. See section 924(e)–(g) of the Public Health Service Act, 42 U.S.C. 299b–24(e)–(g).

This section also describes two circumstances under which an entity will be considered to have voluntarily relinquished its status as a PSO: (1) Notification of the Secretary in writing by the PSO of its intent to relinquish its status voluntarily; and (2) if a PSO lets its period of listing expire without submission of a certification for continued listing that the Secretary has accepted. In both circumstances, we propose that such a PSO consult with the source of the patient safety work product in its possession to provide notice of its intention to cease operations and provide for appropriate disposition of such patient safety work product. When the Secretary removes a PSO from listing as a result of revocation for cause or voluntarily relinquishment, the Secretary is required to provide public notice of the action.

We note that section 921 of the Public Health Service Act, 42 U.S.C. 299b–21, and, therefore, the proposed rule, defines a PSO as an entity that is listed by the Secretary pursuant to the requirements of the statute that are incorporated into this proposed rule. This means that an entity remains a PSO for its three-year period of listing unless the Secretary removes the entity from the list of PSOs because he revokes acceptance of its certification and listing for cause or because the entity voluntarily relinquishes its status as described below. Accordingly, even when a deficiency is identified publicly or the proposed requirements of this section have been initiated, we stress that an entity remains a PSO until the date and time at which the Secretary's removal of the entity from listing is effective. Until then, data that is reported to a listed entity by providers shall be considered patient safety work product and the protections accorded patient safety work product continue to apply following the delisting of the PSO.

(A) Proposed § 3.108(a)—Process for Correction of a Deficiency and Revocation

Proposed § 3.108(a) describes the process by which the Secretary would provide an opportunity for a PSO to correct identified deficiencies and, if not timely corrected or if the deficiencies cannot be ''cured,'' the process that can lead to a determination by the Secretary to revoke acceptance of a PSO's certification. This section proposes a two-stage process. The first stage would provide an opportunity to correct a deficiency. Under the proposal, when the Secretary identifies a deficiency, the Secretary would send the PSO a notice of preliminary determination of a deficiency. The PSO would then have an opportunity to demonstrate that the information on which the notice was based is incorrect. The notice would include a timetable for correction of the deficiency and may specify the specific corrective action and the documentation that the Secretary would need to determine if the deficiency has been corrected. The PSO would be encouraged to provide information for the administrative record on unexpected challenges in correcting the deficiency, since the Secretary has great flexibility to work with a PSO to facilitate correction of deficiencies. We anticipate that most PSO deficiencies would be resolved at this stage.

Under the proposal, the second stage would occur when the Secretary would conclude that a PSO has not timely corrected a deficiency or has a pattern of non-compliance and issues the PSO a notice of proposed revocation and delisting. Rather than requiring a PSO to seek an opportunity to appeal, the proposed rule would provide an automatic period of 30 days for a PSO to be heard in writing by submitting a rebuttal to the findings in the Secretary's notice of revocation and delisting. The Secretary may then affirm, modify, or reverse the notice of revocation and delisting.

In light of the procedures in the proposed rule to ensure due process, we have not proposed to incorporate any further internal administrative appeal process beyond the Secretary's determination regarding a notice of proposed revocation and delisting pursuant to proposed § 3.108(a)(5). We invite comments on our proposed approach.

(1) Proposed § 3.108(a)(1)—Circumstances Leading to Revocation

Proposed § 3.108(a)(1) lists four circumstances, each of which is statutorily based, that may lead the Secretary to revoke acceptance of a PSO's certification and delist the entity: the PSO is not meeting the obligations to which it certified its compliance as required by proposed § 3.102; the PSO has not certified to the Secretary that it has entered the required minimum of two contracts within the applicable 24-month period pursuant to proposed § 3.102(d)(1); the Secretary, after reviewing a PSO's disclosure statement submitted pursuant to proposed § 3.102(d)(2), determines that the PSO cannot fairly and accurately perform its duties pursuant to proposed § 3.104(c); or the PSO is not in compliance with any other provision of the Patient Safety Act or this proposed part. (See section 924(c) and (e) of the Public Health Service Act, 42 U.S.C. 299b–24(c) and (e).)

(2) Proposed § 3.108(a)(2)—Notice of Preliminary Finding of Deficiency and Establishment of an Opportunity for Correction of a Deficiency

Under proposed § 3.108(a)(2), when the Secretary has reason to believe that a PSO is not in compliance with the requirements of the statute and the final rule, the Secretary would send a written notice of a preliminary finding of deficiency to the PSO (see section 924(c) and (e) of the Public Health Service Act, 42 U.S.C. 299b–24(c) and (e)). The notice would specifically state the actions or inactions that describe the deficiency, outline the evidence that a deficiency exists, specify the possible and/or required corrective action(s) that must be taken, establish an opportunity for correction and a date by which the corrective action(s) must be completed, and, in certain circumstances, specify the documentation that the PSO would be required to submit to demonstrate that the deficiency has been corrected.

We propose that, absent other evidence of actual receipt, we would assume that the notice of a preliminary finding of deficiency has been received 5 calendar days after it was sent. Under the proposal, if a PSO submits evidence to the Secretary that demonstrates to the Secretary that the preliminary finding is factually incorrect within 14 calendar days following receipt of this notice, the preliminary finding of deficiency would be withdrawn; otherwise, it would be the basis for a finding of deficiency. We stress that this would not be an opportunity to file an appeal regarding the proposed corrective actions, the period allotted for correcting the deficiency, or the time to provide explanations regarding why a deficiency exists. This 14-day period would only ensure that the PSO has an opportunity,

if the information on which the notice is based is not accurate, to correct the record immediately. For example, a notice of a preliminary finding of deficiency may be based on the fact that the Secretary has no record that the PSO has entered the required two contracts. In this case, if a PSO can attest that it submitted the certification as required or can attest that it has entered the required two contracts consistent with the requirements of proposed § 3.102(d)(1), the Secretary would then withdraw the notice. If a notice of deficiency is based on the failure of the PSO to submit a required disclosure statement within 45 days, the PSO might submit evidence that the required statement had been sent as required. If the evidence is convincing, the Secretary would withdraw the notice of preliminary finding of deficiency. If the Secretary does not consider the evidence convincing, the Secretary would so notify the PSO and the notice would remain in effect. The PSO would then need to demonstrate that it has met the requirements of the notice regarding correction of the deficiency.

We anticipate that in the vast majority of circumstances in which the Secretary believes there is a deficiency, the deficiency can and will be corrected by the PSO. In those cases, as discussed above, the PSO will be given an opportunity to take the appropriate action to correct the deficiency, and avoid revocation and delisting. However, we can anticipate situations in which a PSO's conduct is so egregious that the Secretary's acceptance of the PSO's certification should be revoked without the opportunity to cure because there is no meaningful cure. An example would be where a PSO has a policy and practice of knowingly and inappropriately selling patient safety work product or where the PSO is repeatedly deficient and this conduct continues despite previous opportunities to cure. We are considering adding a provision whereby an opportunity to ''cure'' would not be available in this type of situation. Providing the PSO with an opportunity for correction, as provided in the Patient Safety Act, would entail providing an opportunity to correct the preliminary factual findings of the Department. Thus, the PSO would have the chance to demonstrate that we have the facts wrong or there are relevant facts we are overlooking. We invite comments regarding this approach and how best to characterize the situations in which the opportunity to ''cure'' (e.g., to change policies, practices or procedures, sanction employees, send out correction notices) would not be sufficient, meaningful, or appropriate.

(3) Proposed § 3.108(a)(3)—Determination of Correction of a Deficiency

Proposed section § 3.108(a)(3) addresses the determination of whether a deficiency has been corrected, including the time frame for submission of the required documentation that the deficiency has been corrected, and the actions the Secretary may take after review of the documentation and any site visit(s) the Secretary deems necessary or appropriate (see sections 924(c) and (e) of the Public Health Service Act, 42 U.S.C. 299b–24(c) and (e)).

Under the proposal, during the period of correction, we would encourage the PSO to keep the Department apprised in writing of its progress, especially with respect to any challenges it faces in implementing the required corrective actions. Such communications would become part of the administrative record. Until there is additional experience with the operational challenges that PSOs face in implementing specific types of corrective actions, such information, if submitted, would be especially helpful for ensuring that the time frames and the corrective actions specified by the Secretary are reasonable and appropriate. As noted below, such information would be considered by the Secretary in making a determination regarding a PSO's compliance with the correction of a deficiency. Unless the Secretary specifies a different submission date, or approves such a request from the PSO, we propose that documentation submitted by the PSO to demonstrate correction of the deficiency must be received by the Secretary no later than 5 calendar days after the final day of the correction period.

Under the proposed rule, in making a determination, the Secretary would consider the documentation and other information submitted by the PSO, the findings of any site visit that might have been conducted, recommendations of program staff, and any other information available regarding the PSO that the Secretary deems appropriate. After completing his review, the Secretary may make one of the following determinations: (1) The action(s) taken by the PSO have corrected any deficiency, in which case the Secretary will withdraw the notice of deficiency and so notify the PSO; (2) the PSO has acted in good faith to correct the deficiency but an additional period of time is necessary to achieve full compliance and/or the required corrective action specified in the notice of a preliminary finding of deficiency needs to be modified in light of the actions undertaken by the PSO so far, in which case the Secretary will extend the period for correction and/or modify the specific corrective action required; or (3) the PSO has not completed the corrective action because it has not acted with reasonable diligence or timeliness to ensure that the corrective action was completed within the allotted time, in which case the Secretary will issue to the PSO a notice of proposed revocation and delisting.

When the Secretary issues a notice of proposed revocation and delisting, this notice would include those deficiencies that have not been timely corrected. The notice would be accompanied by information concerning the manner in which the PSO may exercise its opportunity to be heard in writing to respond to the deficiency findings described in the notice.

(4) Proposed § 3.108(a)(4)—Opportunity to be Heard in Writing Following a Notice of Proposed Revocation and Delisting

Proposed § 3.108(a)(4) sets forth our approach to meeting the statutory requirement established in section 924(e) of the Public Health Service Act, 42 U.S.C. 299b–24(e), for a PSO to have an opportunity to dispute the findings of deficiency in a notice of proposed revocation and delisting.

Absent other evidence of actual receipt, we would assume that the notice of proposed revocation and delisting has been received by a PSO five calendar days after it was sent. Under the proposed rule, unless a PSO chooses to waive its right to contest a notice of proposed revocation and delisting and so notifies the Secretary, a PSO would not need to request an opportunity to appeal a notice of proposed revocation and delisting. A PSO would automatically have 30 calendar days, beginning the day the notice is deemed to be received, to exercise its opportunity to be heard in writing. The Secretary would consider, and include in the administrative record, any written information submitted by the PSO within this 30-day period that responds to the deficiency findings in the notice of proposed revocation and delisting. If a PSO does not take advantage of the opportunity to submit a substantive response in writing within 30 calendar days of receipt of the notice of proposed revocation and delisting, the notice would become final as a matter of law at midnight of the date specified by the Secretary in the notice. The Secretary

would provide the PSO with policies and rules of procedures that govern the form or transmission of the written response to the notice of proposed revocation and delisting.

We are considering incorporating in the final rule an exception to our proposed policy of automatically providing a PSO with a 30-day period in which to submit a written response to a notice of proposed revocation and delisting. The one exception we are considering relates to failure to meet the requirement for a minimum of two contracts. The statutory requirement is unambiguous that this requirement must be met within every 24-month period after the initial date of listing of the PSO. We propose elsewhere that a PSO submit its notification 45 calendar days early so that a period for correction can be established that concludes at midnight of the last day of the applicable 24-month period established by the statute for compliance. The Secretary would then need to receive notification from a PSO that this requirement has been met no later than midnight of that last day (see proposed § 3.102(d)(1) and proposed § 3.104(b)). Other than verifying that the PSO has not entered into and reported the required two bona fide contracts by midnight on the last day of the applicable 24-month period, we see no basis for a written rebuttal of such a deficiency determination. The language we are considering, therefore, would authorize the Secretary, when the basis for a notice of proposed revocation and delisting is the failure of a PSO to meet this very specific requirement, to proceed to revocation and delisting five calendar days after the notice of proposed revocation and delisting would be deemed to have been received.

(5) Proposed § 3.108(a)(5)—The Secretary's Decision Regarding Revocation

If a written response to the deficiency findings of a notice of proposed revocation and delisting is submitted by a PSO, proposed § 3.108(a)(5) provides that the Secretary will review the entire administrative record pertaining to the notice of proposed revocation and delisting and any written materials submitted by the PSO under proposed § 3.108(a)(4). The Secretary may affirm, reverse, or modify the notice of proposed revocation and delisting. The Secretary will notify the PSO in writing of his decision with respect to any revocation of the acceptance of its certification and its continued listing as a PSO. (See section 924(e) of the Public Health Service Act, 42 U.S.C. 299b–24(e).)

(B) Proposed § 3.108(b)—Revocation of the Secretary's Acceptance of a PSO's Certification

When the Secretary makes a determination to remove the listing of a PSO for cause pursuant to proposed § 3.108(a), proposed § 3.108(b) specifies the actions that the Secretary and the entity must take, and implements the protections that the statute affords to data submitted to such an entity.

(1) Proposed § 3.108(b)(1)—Establishing Revocation for Cause

Under our proposal, after following the requirements of proposed § 3.108(a), if the Secretary determines pursuant to paragraph (a)(5) of this section that revocation of the acceptance of a PSO's certification is warranted for failure to comply with the requirements of the Patient Safety Act, or the regulations implementing the Patient Safety Act, the Secretary would establish, and notify the PSO of, the date and time at which the Secretary will revoke the acceptance of its certification and remove the entity from the list of PSOs. The Secretary may include information in the notice on the statutory requirements, incorporated in proposed § 3.108(b)(2) and § 3.108 (b)(4) and discussed below, that apply to the entity following the Secretary's actions, and the Secretary would provide public notice as required by proposed § 3.108(d).

(2) Proposed § 3.108(b)(2)—Required Notification of Providers and Status of Data

Proposed § 3.108(b)(2) incorporates in the proposed rule the statutory requirements that are intended to ensure that providers receive a reasonable amount of notice that the PSO with which they are working is being removed from the list of PSOs (section 924(e)(2) of the Public Health Service Act, 42 U.S.C. 299b–24(e)(2)) and to clarify the status of data submitted by providers to a PSO whose listing has been revoked (section 924(f) of the Public Health Service Act, 42 U.S.C. 299b–24(f)).

As required by the statute, within 15 calendar days of the date established in the Secretary's notification of action under paragraph (b)(1) of this section, the entity subject to proposed § 3.108(b)(1) shall confirm to the Secretary that it has taken all reasonable actions to notify each provider whose patient safety work product has been collected or analyzed by the PSO that the entity has been removed from the list of PSOs. We would recommend, but do not propose to require, that PSOs make a priority of notifying providers who report most frequently to the PSO, especially providers with contracts with the PSO. These providers would need to close out any current contract they have with the PSO, determine if they wish to enter a contract with another PSO, and if so, they would need time to identify another PSO and then negotiate another contract.

We also recognize that, even when this statutory notification requirement is met, the notification period is short. While we do not have the authority to require a PSO to undertake notification of providers more quickly than the statute specifies, we invite comment on whether there are any other steps the Secretary should take to ensure that affected providers receive timely notice. We are considering requiring notice by electronic or priority mail if no notice has been given at the end of seven days.

Confidentiality and privilege protections that applied to patient safety work product while the former PSO was listed continue to apply after the entity is removed from listing. Furthermore, section 924(f)(1) of the Public Health Service Act, 42 U.S.C. 299b–24(f)(1) provides that data submitted to an entity within 30 calendar days of the date on which acceptance of its certification is revoked and it is removed from the list of PSOs, shall have the same status as data submitted while the entity was still listed. Thus, data that would otherwise be patient safety work product had it been submitted while the PSO was listed, will be protected as patient safety work product if submitted during this 30-day period after delisting.

We stress that the statutory language in section 924(f)(1) of the Public Health Service Act, 42 U.S.C. 299b–24(f)(1), pertains only to data submitted to such an entity within 30 calendar days after such revocation and removal. This provision does not enable an entity that has been removed from listing to generate patient safety work product on its own pursuant to section 921(7)(A)(i)(II) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(A)(i)(II); the entity loses that authority on the effective date and time of the Secretary's action to remove it from listing.

(3) Proposed § 3.108(b)(3)—Disposition of Patient Safety Work Product and Data

Proposed § 3.108(e) incorporates in the proposed rule statutory requirements regarding the disposition of patient safety work product or data following revocation and delisting of a PSO (section 924(g) of the Public Health Service Act, 42 U.S.C. 299b–24(g)). This proposed subsection would require that the former PSO provide for the

disposition of patient safety work product or data in its possession in accordance with one or more of three alternatives described in section 924(g) of the Public Health Service Act, 42 U.S.C. 299b–24(g). The three alternatives include: transfer of the patient safety work product with the approval of the source from which it was received to a PSO which has agreed to accept it; return of the patient safety work product or data to the source from which it was received; or, if return is not practicable, destroy such work product or data.

The text of the proposed rule refers to the ''source'' of the patient safety work product or data that is held by the former PSO, which is a broader formulation than the statutory phrase ''received from another entity.'' While the statutory requirement encompasses PSOs as well as institutional providers, we tentatively conclude that the underlying intent of this statutory provision is to require the appropriate disposition of patient safety work product from all sources, not merely institutional sources. We note that the statute, and therefore the proposed rule, permits individual providers to report data to PSOs and individual providers are able to enter the same type of ongoing arrangements, or contractual arrangements, as institutional providers. Moreover, proposed § 3.108(b)(2) would require PSOs to notify all providers (individual as well as institutional providers) from whom they receive data about the Secretary's revocation and delisting decision. We preliminarily conclude, therefore, that it is consistent with the statute that a former PSO consult with all sources (individuals as well as entities) regarding the appropriate disposition of the patient safety work product or data that they supplied. Moreover, it is a good business practice. If workforce members of a former PSO retain possession of any patient safety work product, they would incur obligations and potential liability if it is impermissibly disclosed. We welcome comments on our interpretation.

The statutory provision indicates that these requirements apply to both patient safety work product or 'data' described in 924(f)(1) of the Public Health Service Act, 42 U.S.C. 299b–24(f)(1). Subsection (f)(1), entitled 'new data' and incorporated in proposed § 3.108(b)(2), describes data submitted to an entity within 30 calendar days after the entity is removed from listing as a PSO and provides that this data ''shall have the same status as data submitted while the entity was still listed.'' The proposed regulation mirrors this formulation.

While the statute and this proposed rule would permit destruction of patient safety work product, we would encourage entities that have their listing as a PSO revoked to work with providers to ensure that patient safety work product remains available for aggregation and further analysis whenever possible, either by returning it to the provider or, with concurrence of the provider, transferring it to a PSO willing to accept it.

The statute does not establish a time frame for a PSO subject to revocation and delisting to complete the disposition of the patient safety work product or data in its possession. We invite comment on whether we should include a date by which this requirement must be completed (for example, a specific number of months after the date of revocation and delisting).

(C) Proposed § 3.108(c)—Voluntary Relinquishment

The statute recognizes the right of an entity to relinquish voluntarily its status as a PSO, in which case the Secretary will remove the entity from the list of PSOs. See section 924(d) of the Public Health Service Act, 42 U.S.C. 299b–24(d).

We stress that, if the Secretary determines that an entity has relinquished voluntarily its status as a PSO and removes the entity from listing, the confidentiality and privilege protections that applied to patient safety work product while the former PSO was listed continue to apply after the entity is removed from listing.

(1) Proposed § 3.108(c)(1)—Circumstances Constituting Voluntary Relinquishment

Proposed § 3.108(c)(1) provides that an entity would be considered to have relinquished voluntarily its status as a PSO under two circumstances: when a PSO advises the Secretary in writing that it no longer wishes to be a PSO, and when a PSO permits its three-year period of listing to expire without timely submission of the required certification to the Secretary for continued listing. To ensure that such a lapse is not inadvertent, we provide in proposed § 3.104(e)(2) that the Secretary would send a notice of imminent expiration to any PSO from which the Secretary has not received a certification for continued listing by the date that is 45 calendar days before the expiration of its current period of listing. This notice is intended to ensure that the PSO has sufficient time to submit a certification for continued listing if it chooses to do so and that, if a lapse occurs, it is not inadvertent.

(2) Proposed § 3.108(c)(2)—Notification of Voluntary Relinquishment

Proposed § 3.108(c)(2) would require an entity that seeks to relinquish voluntarily its status as a PSO to include attestations in its notice to the Secretary that it has made all reasonable efforts to provide for the orderly termination of the PSO. First, the PSO must attest that it has made—or will have made within 15 calendar days of the date of this notification to the Secretary—all reasonable efforts to notify organizations or individuals who have submitted data to the PSO of its intent to cease operation and to alert providers that they should cease reporting or submitting any further information as quickly as possible.

We preliminarily conclude that, when a PSO voluntarily relinquishes its status, data submitted by providers to the entity after the date on which the Secretary removes it from listing is not patient safety work product. The statutory provision, incorporated in the proposed rule at § 3.108(b)(2), that permits providers to submit data to an entity for an additional 30 days after the date of its removal from listing applies only to PSOs for which the Secretary has revoked acceptance of its certification for cause. It does not apply to a PSO that voluntarily relinquishes its status. We welcome comment on our interpretation.

Second, the PSO would be required to attest that, in consultation with the organizations or individuals who submitted the patient safety work product in its possession, it has established—or will have made all reasonable efforts within 15 calendar days of the date of this notification to establish—a plan for the appropriate disposition of such work product, consistent to the extent possible with the statutory requirements incorporated in proposed § 3.108(b)(3). Finally, the individual submitting the notification of voluntary relinquishment would provide appropriate contact information for further communications that the Secretary deems necessary.

We caution any PSO considering voluntary relinquishment that its status remains in effect until the Secretary removes the entity from listing. The PSO's responsibilities, including those related to the confidentiality and security of the patient safety work product or data in its possession, are not discharged by the decision of a PSO to cease operations. Accordingly, we urge PSOs that are experiencing financial distress or other circumstances that may

lead to voluntary relinquishment, to contact AHRQ program staff as early as possible so that the PSO's obligations can be appropriately discharged.

(3) Proposed § 3.108(c)(3)—Response to Notification of Voluntary Relinquishment

In response to the submission of a notification of voluntary relinquishment, proposed § 3.108(c)(3) provides that the Secretary would respond in writing and indicate whether the proposed voluntary relinquishment is accepted. We anticipate that the Secretary would normally approve such requests but the text provides the Secretary with discretion to accept or reject such a request from a PSO that seeks voluntary relinquishment during or immediately after revocation proceedings. Our proposal is intended to recognize that, in certain circumstances, for example, when the deficiencies of the PSO are significant or reflect a pattern of non-compliance with the Patient Safety Act or the proposed rule, the Secretary may decide that giving precedence to the revocation process may be more appropriate.

(4) Proposed § 3.108(c)(4)—Implied Voluntary Relinquishment

Proposed § 3.108(c)(4) enables the Secretary to determine that implied voluntary relinquishment has taken place if a PSO permits its period of listing to expire without receipt and acceptance by the Secretary of a certification for continued listing. In our view, the statute does not permit an entity to function as a PSO beyond its 3-year period of listing unless it has submitted, and the Secretary has accepted, a certification for a 3-year period of continued listing. To ensure that such a lapse is not inadvertent, we propose a requirement in § 3.104(e)(2) that the Secretary would send a notice of imminent expiration to any PSO from which the Secretary has not received the required certification for continued listing by the date that is 45 calendar days prior to the last date of the PSOs current period of listing. Accordingly, we propose that the Secretary would determine that a PSO under these circumstances has relinquished voluntarily its status at midnight on the last day of its current period of listing, remove the entity from the list of PSOs at midnight on that day, make reasonable efforts to notify the entity in writing of the action taken, and promptly provide public notice in accordance with proposed § 3.108(d).

Under the proposed rule, the notice of delisting would request that the entity make reasonable efforts to comply with the requirements of proposed § 3.108(c)(2). Compliance with these requirements in this circumstance would mean that the former PSO would be required to notify individuals and organizations that routinely reported data to the entity during its period of listing that it has voluntarily relinquished its status as a PSO and that they should no longer report or submit data, and make reasonable efforts to provide for the disposition of patient safety work product or data in consultation with the sources from which such information was received in compliance with the statutory requirements incorporated in proposed § 3.108(b)(3)(i)–(iii). The former PSO would also be expected to provide appropriate contact information for further communications from the Secretary.

We are aware that, if a PSO does not give appropriate notice to providers from which it receives data, that it does not intend to seek continued listing, this could jeopardize protections for data that these providers continue to report. To address this issue, we are seeking comment in proposed § 3.104(e) on a proposal that would ensure that providers have advance notice that a PSO is approaching the end of its period of listing but has not yet sought continued listing.

(5) Proposed § 3.108(c)(5)—Non-Applicability of Certain Procedures and Requirements

Proposed § 3.108(c)(5) provides that neither a decision by a PSO to notify the Secretary that it wishes to relinquish voluntarily its status as a PSO, nor a situation in which a PSO lets its period of listing lapse, constitutes a deficiency as referenced in the discussion regarding proposed § 3.108(a). As a result, neither the procedures and requirements that apply to the Secretary or a PSO subject to the revocation process outlined in that proposed subsection, nor the requirements that apply to the Secretary or a PSO following action by the Secretary pursuant to proposed § 3.108(b)(1), would apply in cases of voluntary relinquishment. Adoption of this proposal would mean that a PSO has no basis for appealing decisions of the Secretary in response to a request for voluntary relinquishment or challenging its removal from listing if its period of listing lapses and the Secretary determines that implied voluntary relinquishment has occurred. We specifically welcome comment on this proposal.

(D) Proposed § 3.108(d)—Public Notice of Delisting Regarding Removal From Listing

Proposed § 3.108(d) incorporates in the proposed rule the statutory requirement that the Secretary must publish a notice in the **Federal Register** regarding the revocation of acceptance of certification of a PSO and its removal from listing pursuant to proposed § 3.108(b)(1) (see section 924(e)(3) of the Public Health Service Act, 42 U.S.C. 299b–24(e)(3)). This proposal also would require the Secretary to publish such a notice if delisting results from a determination of voluntary relinquishment pursuant to proposed § 3.108(c)(3) or (c)(4). The Secretary would specify the effective date and time of the actions in these notices.

5. Proposed § 3.110—Assessment of PSO Compliance

Proposed § 3.110 provides that the Secretary may request information or conduct spot-checks (reviews or site visits to PSOs that may be unannounced) to assess or verify PSO compliance with the requirements of the statute and this proposed subpart. We anticipate that such spot checks will involve no more than 5–10% of PSOs in any year. The legislative history of patient safety legislation in the 108th and 109th Congress suggests that the Senate Health, Education, Labor and Pensions (HELP) Committee assumed that the Secretary had the inherent authority to undertake inspections as necessary to ensure that PSOs were meeting their obligations under the statute. In fact, in reporting legislation in 2004, the Senate HELP Committee justified its proposal for an expedited process for listing PSOs—that is substantially the same as the one incorporated in the Patient Safety Act that was enacted in 2005 and is incorporated in this proposed rule—on the basis that the Secretary could and would be able to conduct such inspections.

The ability of the Secretary to ''examine any organization at any time to see whether it in fact is performing those required activities'' the Senate HELP Committee wrote, enables the Committee to ''strike the right balance'' in adopting an expedited process for the listing of PSOs by the Secretary (Senate Report 108–196). Accordingly, we tentatively conclude that this proposed authority for undertaking inspections on a spot-check basis is consistent with Congressional intent and the overall approach of the proposed rule of using regulatory authority sparingly.

While patient safety work product would not be a focus of inspections conducted under this proposed authority, we recognize that it may not be possible to assess a PSO's compliance with required patient safety activities without access to all of a PSO's records, including some patient safety work product. This proposed section references the broader authority of the Department to access patient safety work product as part of its proposed implementation and enforcement of the Patient Safety Act.

We also note that the inspection authority of this proposed subpart is limited to PSOs and does not extend to providers.

6. Proposed § 3.112—Submissions and Forms

Paragraphs (a) and (b) of proposed § 3.112 explain how to obtain forms and how to submit applications and other information under the proposed regulations. Also, to help ensure the timely resolution of incomplete submissions, proposed paragraph (c) of this section would provide for requests for additional information if a submission is incomplete or additional information is needed to enable the Secretary to make a determination on the submission.

C. Subpart C—Confidentiality and Privilege Protections of Patient Safety Work Product

Proposed Subpart C would establish the general confidentiality protections for patient safety work product, the permitted disclosures, and the conditions under which the specific protections no longer apply. The proposed Subpart also establishes the conditions under which a provider, PSO, or responsible person must disclose patient safety work product to the Secretary in the course of compliance activities, and what the Secretary may do with such information. Finally, proposed Subpart C establishes the standards for nonidentifiable patient safety work product.

The privilege and confidentiality protections set forth in this proposed Subpart apply to the PSO framework established by the Patient Safety Act and this proposed Part, which will involve providers, PSOs, and responsible persons who possess patient safety work product. The Patient Safety Act and this proposed Subpart seek to balance key objectives. First, it seeks to address provider concerns about the potential for damage from unauthorized release of such information, including the potential for the information to serve as a roadmap for provider liability from negative patient outcomes. Second, it seeks to promote the sharing of information about adverse patient safety events among providers and PSOs for the purpose of learning from those events to improve patient safety and creating a culture of safety. To address these objectives, the Patient Safety Act established that patient safety work product would be confidential and privileged, with certain exceptions. Thus, the Patient Safety Act allows sharing of patient safety work product for certain purposes, including for patient safety activities, but simultaneously attaches strict confidentiality and privilege protections for that patient safety work product. To further strengthen the confidentiality protections, the Patient Safety Act imposes significant monetary penalties for violation of the confidentiality provisions, as set forth in proposed Subpart D.

Moreover, patient safety work product that is disclosed generally continues to be privileged and confidential, that is, it may only be permissibly disclosed by the receiving entity or person for a purpose permitted by the Patient Safety Act and this proposed Subpart. The only way that patient safety work product is no longer confidential is if the patient safety work product disclosed is nonidentifiable or when an exception to continued confidentiality exists. See section 922(d)(2)(B) of the Public Health Service Act, 42 U.S.C. 299b–22(d)(2)(B). A person disclosing such work product outside of these statutory permissions in violation of the Patient Safety Act and this proposed Subpart may be subject to civil money penalties.

Proposed § 3.204, among other provisions, provides that patient safety work product is privileged and generally shall not be admitted as evidence in Federal, State, local, or Tribal civil, criminal or administrative proceedings and shall not be subject to a subpoena or order, unless an exception to the privilege applies; the exceptions are discussed in proposed § 3.204(b). Proposed § 3.206 provides that patient safety work product is confidential and shall not be disclosed except as permitted in accordance with the disclosures described in proposed §§ 3.206(b)–(e), 3.208 and 3.210. Under proposed § 3.208, patient safety work product continues to be privileged and confidential after disclosure with certain exceptions. Under proposed § 3.210, providers, PSOs, and responsible persons must disclose to the Secretary such patient safety work product as required by the Secretary for the purposes of investigating or determining compliance with this proposed Part, enforcing the confidentiality provisions, or making determinations on certifying and listing PSOs. Proposed § 3.210 also provides for disclosure to the Secretary. Proposed § 3.212 describes the standard for determining that patient safety work product is nonidentifiable.

Throughout the proposed rule, the term patient safety work product means both identifiable patient safety work product and nonidentifiable patient safety work product, unless otherwise specified. In addition, if a disclosure is made by or to a workforce member of an entity, it will be considered a disclosure by or to the entity itself.

Finally, throughout our discussion we note the relationship between the Patient Safety Act and the HIPAA Privacy Rule. Several provisions of the Patient Safety Act recognize that the patient safety regulatory scheme will exist alongside other requirements for the use and disclosure of protected health information under the HIPAA Privacy Rule. For example, the Patient Safety Act establishes that PSOs will be business associates of providers, incorporates individually identifiable health information under the HIPAA Privacy Rule as an element of identifiable patient safety work product, and adopts a rule of construction that states the intention not to alter or affect any HIPAA Privacy Rule implementation provision (see section 922(g)(3) of the Public Health Service Act, 42 U.S.C. 299b–22(g)(3)). We anticipate that most providers reporting to PSOs will be HIPAA covered entities under the HIPAA Privacy Rule, and as such, will be required to recognize when requirements of the HIPAA Privacy Rule apply. Because this proposed rule focuses on disclosures of identifiable patient safety work product which may include protected health information, we discuss where appropriate the overlaps between the proposed Patient Safety Act permitted disclosures and the existing HIPAA Privacy Rule use and disclosure permissions.

1. Proposed § 3.204—Privilege of Patient Safety Work Product

Proposed § 3.204 describes the privilege protections of patient safety work product and when the privilege protections do not apply. The Patient Safety Act does not give authority to the Secretary to enforce breaches of privilege protections. Rather, we anticipate that the tribunals, agencies or professional disciplinary bodies before whom these proceedings take place will

adjudicate the application of privilege as set forth in section 922(a)(1)–(5) of the Public Health Service Act, 42 U.S.C. 299b–22(a)(1)–(5). Even though the privilege protections will be enforced through the court systems, and not by the Secretary, we repeat the statutory privilege provisions and exceptions for convenience. We note, however, that the same exceptions are repeated in the confidentiality context, which the Secretary does enforce; so these are repeated at proposed § 3.206 and such impermissible disclosure may be penalized under proposed Subpart D.

To determine the permissible scope of disclosures under the Patient Safety Act, it is important to understand the application of the privilege protection and its exceptions described in conjunction with the related proposed confidentiality disclosures. The admission of patient safety work product as evidence in a proceeding or through a subpoena, court order or any other exception to privilege, whether permissibly or not, amounts to a disclosure of that patient safety work product to all parties receiving or with access to the patient safety work product admitted. Thus, we use the term disclosure to describe the transfer of patient safety work product pursuant to an exception to privilege, as well as to an exception to confidentiality. In addition, although the Secretary does not have authority to impose civil money penalties for violations of the privilege protection, a violation of privilege may also be a violation of the confidentiality provisions. For these reasons, we include the privilege language in the proposed implementing regulations.

Finally, as discussed in proposed § 3.204(c), we include a regulatory exception to privilege for disclosures to the Secretary for the purpose of enforcing the confidentiality provisions and for making or supporting PSO certification or listing decisions.

(A) Proposed § 3.204(a)—Privilege

Proposed § 3.204(a) would repeat the statutory language at section 922(a) of the Public Health Service Act, 42 U.S.C. 299b–22(a), establishing the general principle that patient safety work product is privileged and is not subject to Federal, State or local civil, criminal or administrative proceedings or orders; is not subject to disclosure under the Freedom of Information Act or similar Federal, State or local laws; and may not be admitted into evidence in any Federal, State or local civil, criminal or administrative proceeding or the proceedings of a disciplinary body established or specifically authorized under State law. In addition, we have clarified that patient safety work product shall be privileged and not subject to use in Tribal courts or administrative proceedings. Because the Patient Safety Act is a statute of general applicability, it applies to Indian Tribes. In addition, the application of the Federal privilege to Tribal proceedings implements the strong privilege protections intended under section 922 of the Public Health Service Act, 42 U.S.C. 299b–22. (See section 922(g)(1)–(2) of the Public Health Service Act, 42 U.S.C. 299b–22(g)(1)–(2), preserving more stringent Federal, State, and local confidentiality laws).

(B) Proposed § 3.204(b)—Exceptions to Privilege

Proposed § 3.204(b) describes the exceptions to the privilege protection at proposed § 3.204(a) that are established in section 922(c) of the Public Health Service Act, 42 U.S.C. 299b–22(c), as added by the Patient Safety Act. When the conditions set forth in proposed § 3.204(b) are met, then privilege does not apply and would not prevent the patient safety work product from, for example, being entered into evidence in a proceeding or subject to discovery. In all cases, the exceptions from privilege are also exceptions from confidentiality. For proposed § 3.204(b)(1)–(4) and § 3.204(c), we discuss the scope of the applicable confidentiality protection in proposed § 3.206(b) and § 3.206(d).

(1) Proposed § 3.204(b)(1)—Criminal Proceedings

Proposed § 3.204(b)(1) would permit disclosure of identifiable patient safety work product for use in a criminal proceeding, as provided in section 922(c)(1)(A) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(1)(A). Such patient safety work product is not subject to the privilege prohibitions described in proposed § 3.204(a) or the confidentiality protection described in proposed § 3.206(a). See proposed § 3.206(b)(1). Prior to a court determining that an exception to privilege applies pursuant to this provision, a court must make an in camera determination that the identifiable patient safety work product sought for disclosure contains evidence of a criminal act, is material to the proceeding, and is not reasonably available from other sources. See section 922(c)(1)(A) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(1)(A). We discuss in full the requirements of this disclosure under the confidentiality disclosure discussion below.

(2) Proposed § 3.204(b)(2)—Equitable Relief for Reporters

Proposed § 3.204(b)(2) permits the disclosure of identifiable patient safety work product to the extent required to carry out the securing and provision of specified equitable relief as provided for under section 922(f)(4)(A) of the Public Health Service Act, 42 U.S.C. 299b–22(f)(4)(A). This exception is based on section 922(c)(1)(B) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(1)(B). The Patient Safety Act permits this disclosure as an exception to privilege and confidentiality to effectuate the provision that authorizes equitable relief for an employee who has been subjected to an adverse employment action for good faith reporting of information to a PSO directly or to a provider for the intended report to a PSO. We discuss in full the requirements of this disclosure under the confidentiality disclosure discussion below.

(3) Proposed § 3.204(b)(3)—Authorized by Identified Providers

Proposed § 3.204(b)(3) describes when identifiable patient safety work product may be excepted from privilege when each of the providers identified in the patient safety work product authorizes the disclosure. This provision is based on section 922(c)(1)(C) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(1)(C). Such patient safety work product is also not subject to the confidentiality protections described in proposed § 3.206(a). We discuss in full the requirements of this disclosure under the confidentiality disclosure discussion below.

(4) Proposed § 3.2049(b)(4)—Nonidentifiable Patient Safety Work Product

Proposed § 3.204(b)(4) permits patient safety work product to be excepted from privilege when disclosed in nonidentifiable form. This provision is based on section 922(c)(3) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(3). As with other privilege protections, we expect the tribunals for which the information is sought to adjudicate the application of this exception. We discuss in full the requirements of this disclosure in the confidentiality disclosure discussion below.

(C) Proposed § 3.204(c)—Implementation and Enforcement of the Patient Safety Act

Proposed § 3.204(c) excepts from privilege disclosures of relevant patient safety work product to or by the Secretary as needed for investigation or determining compliance with this Part

or for enforcement of the confidentiality provisions, or for making or supporting PSO certification or listing decisions, under the Patient Safety Act. We propose that the Secretary may use and disclose patient safety work product when pursuing civil money penalties for impermissible disclosures. This is a privilege exception in the same manner as exceptions listed in proposed § 3.204(b), but we state it separately to provide specific emphasis for the inclusion of this exception to privilege by the Secretary for enforcement activities. This information is also a permissible disclosure under proposed § 3.206(d), discussed below.

The Patient Safety Act provides for broad privilege and confidentiality protections, as well as the authority for the Secretary to impose civil money penalties on persons who knowingly or recklessly disclose identifiable patient safety work product in violation of those protections. However, in order to perform investigations and compliance reviews to determine whether a violation has occurred, the Secretary may need to have access to privileged and confidential patient safety work product.

We believe that Congress could not have intended that the privilege and confidentiality protections afforded to patient safety work product operate to frustrate the sole enforcement mechanism Congress provided for the punishment of impermissible disclosures and to preclude the imposition of civil money penalties. As a matter of public policy, the creation of a confidentiality protection is meaningless without the capacity to enforce a breach of those protections. For these reasons, we propose a privilege exception narrowly drawn to permit the Secretary to perform the enforcement and operational duties required by the Patient Safety Act, which include the submission of patient safety work product to administrative law judges (ALJs), the Departmental Appeals Board (Board), and the courts.

This proposed provision would permit the disclosure of patient safety work product to the Secretary or disclosure by the Secretary so long as such disclosure is for the purpose of implementation and enforcement of these proposed regulations. Such disclosure would include the introduction of patient safety work product into proceedings before ALJs or the Board under proposed Subpart D by the Secretary, as well as the disclosure during investigations by OCR or activities in reviewing PSO certifications by AHRQ. Moreover, disclosures of patient safety work product made to the Board or other parts of the Department that are received by workforce members, such as contractors operating electronic web portals or mail sorting and paper scanning services, would be permitted as a disclosure to the Secretary under this proposed provision. This provision would also permit the Board to disclose any patient safety work product in order to properly review determinations or to provide records for court review.

Patient safety work product disclosed under this exception remains protected by both privilege and confidentiality protections as proposed in § 3.208. This exception does not limit the ability of the Secretary to disclose patient safety work product in accordance with the exceptions under proposed § 3.206(b) or this Part. Rather, this proposed section provides a specific permission by which patient safety work product may be disclosed to the Secretary and the Secretary may further disclose such patient safety work product for compliance and enforcement purposes.

We believe strongly in the protection of patient safety work product as provided in the Patient Safety Act and the proposed regulation, and seek to minimize the risk of improper disclosure of patient safety work product by using and disclosing patient safety work product only in limited and necessary circumstances. We intend that any disclosure made pursuant to this proposed provision be limited in the amount of patient safety work product disclosed to accomplish the purpose of implementation, compliance, and enforcement. Proposed § 3.312 discusses the limitations on what the Secretary may do with any patient safety work product obtained pursuant to an investigation or compliance review under proposed Subpart D. As discussed in the preamble to proposed § 3.312, section 922(g)(3) of the Public Health Service Act, 42 U.S.C. 299b–22(g)(3), provides that the Patient Safety Act does not affect the implementation of the HIPAA confidentiality regulations. Accordingly, the privilege provisions in the Patient Safety Act would not bar the Secretary from introducing patient safety work product in a HIPAA enforcement proceeding.

2. Proposed § 3.206—Confidentiality of Patient Safety Work Product

Proposed § 3.206 describes the confidentiality protection of patient safety work product as well as exceptions from confidentiality protection. The following discussion generally refers to an act that falls within an exception from confidentiality as a permissible disclosure.

(A) Proposed § 3.206(a)—Confidentiality

Proposed § 3.206(a) would establish the overarching general principle that patient safety work product is confidential and shall not be disclosed. The principle applies to patient safety work product held by anyone. This provision is based on section 922(b) of the Public Health Service Act, 42 U.S.C. 299b–22(b).

(B) Proposed § 3.206(b)—Exceptions to Confidentiality

Proposed § 3.206(b) describes the exceptions to confidentiality, or the permitted disclosures. Certain overarching principles apply to the proposed confidentiality standards. First, we consider these exceptions to be ''permissions'' to disclose patient safety work product and the holder of the patient safety work product retains full discretion whether or not to disclose. Thus, similar to the disclosures permitted under the HIPAA Privacy Rule, we are defining a uniform federal baseline of protection that is enforceable by federally imposed civil money penalties. We are not encouraging or requiring disclosures, except to the Secretary as provided in this proposed rule. Therefore, a provider, PSO, or responsible person, may create confidentiality policies and procedures with respect to patient safety work product that are more stringent than these proposed rules and are free to otherwise condition the release of patient safety work product that comes within these exceptions by contract, employment relationship, or other means. See, for example, section 922(g)(4) of the Public Health Service Act, 42 U.S.C. 299b–22(g)(4). However, the Secretary will not enforce such policies or private agreements.

Second, when exercising the discretion to disclose patient safety work product, we encourage providers, PSOs, and responsible persons to consider the purposes for which the disclosures are made. Disclosures should be narrow and consistent with the overarching goals of the privilege and confidentiality protections, even though these protections generally continue to apply to patient safety work product after disclosure. We encourage any entity or person making a disclosure to consider both the amount of patient safety work product that is being disclosed, as well as the amount of identifiable information disclosed. Even though not required, entities or persons should attempt to disclose the amount of information commensurate with the

purposes for which a disclosure is made. We encourage the disclosure of the least amount of identifiable patient safety work product that is appropriate for the purpose of the disclosure, which might mean the disclosure of less information than all of the information that would be permitted to be disclosed under the confidentiality provisions. We also encourage the removal of identifiable information when feasible regardless of whether protection under this rule continues. While a provider, PSO, or responsible person need not designate a workforce member to determine when a disclosure of patient safety work product is permitted, such a designation may be a best practice to ensure that a disclosure complies with the confidentiality provisions, and contains the least amount of patient safety work product necessary.

Third, we have addressed the scope of redisclosure by persons receiving patient safety work product. Persons receiving patient safety work product would only be allowed to redisclose that information to the extent permitted by the proposed regulation. For example, we propose that accrediting bodies receiving patient safety work product pursuant to the accrediting body disclosure at proposed § 3.206(b)(8) may not further disclose that patient safety work product. We seek public comment on the subject of whether there are any negative implications associated with limiting redisclosures in this way.

Additionally, agencies subject to both the Patient Safety Act and the Privacy Act, 5 U.S.C. 552a, must comply with both statutes when disclosing patient safety work product. Under the Patient Safety Act, see section 922(b) of the Public Health Service Act, 42 U.S.C. 299b–22(b), if another law, such as the Privacy Act, permits or requires the disclosure of patient safety work product, disclosure of this information would be in violation of the Patient Safety Act unless the Patient Safety Act also permits this disclosure. However, if the Privacy Act prohibits the disclosure of information that is patient safety work product, the permissible disclosure of this information under the Patient Safety Act would be in violation of the Privacy Act. Therefore, for agencies subject to both statutes, patient safety work product must be disclosed in a manner that is permissible under both statutes. The Privacy Act does permit agencies to make disclosures pursuant to established routine uses. See 5 U.S.C. 552a(a)(7); 552a(b)(3); and 552a(e)(4)(D). We recommend that Federal agencies that maintain a Privacy Act system of records containing information that is patient safety work product include routine uses that will permit disclosures allowed by the Patient Safety Act.

Finally, for HIPAA covered entities, when individually identifiable health information is encompassed within the patient safety work product, the disclosure must also comply with the HIPAA Privacy Rule. Thus, for patient safety work product disclosures that contain individually identifiable health information, as defined in 45 CFR 160.103, we note some of the comparable HIPAA Privacy Rule permissions for consideration.

(1) Proposed § 3.206(b)(1)—Criminal Proceeding

Proposed § 3.206(b)(1) would establish the permitted criminal proceeding disclosure which parallels the privilege exception disclosure for use in a criminal proceeding, proposed § 3.204(b)(1). Proposed § 3.206(b)(1) would permit disclosure of identifiable patient safety work product for use in a criminal proceeding. Prior to a court determining that an exception to privilege applies pursuant to this provision, a court must make an in camera determination that the identifiable patient safety work product sought for disclosure contains evidence of a criminal act, is material to the proceeding, and is not reasonably available from other sources. See section 922(c)(1)(A) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(1)(A).

After such determinations by a court, the patient safety work product may be permissibly disclosed within the criminal proceeding. This provision and these limitations are based on section 922(c)(1)(A) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(1)(A). When considering claims that confidentiality protection has been breached, we intend to defer to, and not review, the court's in camera determinations made in context of determining the privilege exception. The Secretary has not been authorized to enforce the underlying privilege protection or make determinations regarding its applicability. The Secretary's authority is limited to investigating and enforcing violations of the confidentiality protections parallel to this privilege exception at proposed § 3.206(b)(1).

The Patient Safety Act establishes that patient safety work product, once disclosed, will generally continue to be privileged and confidential as discussed in proposed § 3.208. See section 922(d)(1) of the Public Health Service Act, 42 U.S.C. 299b–22(d)(1). However, the Patient Safety Act limits the continued protection of the specific patient safety work product disclosed for use in a criminal proceeding. Patient safety work product disclosed for use in a criminal proceeding continues to be privileged and cannot be reused as evidence or in any context prohibited by the privilege protection, but is no longer confidential. See section 922(d)(2)(A) of the Public Health Service Act, 42 U.S.C. 299b–22(d)(2)(A). For example, law enforcement personnel who obtain patient safety work product used in a criminal proceeding may further disclose that patient safety work product because the confidentiality protection does not apply. However, if law enforcement sought to enter the information into another criminal proceeding, it would need a new *in camera* determination for the new criminal proceeding. For a further discussion of continued confidentiality, see discussion of proposed § 3.208 below.

For entities that are subject to the HIPAA Privacy Rule and this Part, disclosures must conform to 45 CFR 164.512(e) of the HIPAA Privacy Rule. We expect that court rulings following an *in camera* determination would be issued as a court order, which would satisfy the requirements of 45 CFR 164.512(e). So long as such legal process is in compliance with 45 CFR 164.512(e), the disclosure would be permissible under the HIPAA Privacy Rule.

(2) Proposed § 3.206(b)(2)—Equitable Relief for Reporters

Proposed § 3.206(b)(2) would permit the disclosure of identifiable patient safety work product to the extent required to carry out equitable relief as provided for under section 922(f)(4)(A) of the Public Health Service Act, 42 U.S.C. 299b–22(f)(4)(A). See section 922(c)(1)(B) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(1)(B). This proposed provision parallels the privilege exception to carry out equitable relief at proposed § 3.204(b)(2). The Patient Safety Act permits this disclosure to effectuate the provision that authorizes an employee to seek redress for adverse employment actions for good faith reporting of information to a PSO directly or to a provider with the intended disclosure to a PSO.

The Patient Safety Act prohibits a provider from taking an adverse employment action against an individual who, in good faith, reports information to the provider for subsequent reporting to a PSO, or to a PSO directly. See section 922(e)(1) of the Public Health Service Act, 42 U.S.C. 299b–22(e)(1). Adverse employment actions are described at section 922(e)(2)

of the Public Health Service Act, 42 U.S.C. 299b–22(e)(2), and include loss of employment, failure to promote, or adverse evaluations or decisions regarding credentialing or licensing. The Patient Safety Act provides adversely affected reporters a civil right of action to enjoin such adverse employment actions and obtain other equitable relief, including back pay or reinstatement, to redress the prohibited actions. As part of that right to seek equitable relief, the Patient Safety Act provides that patient safety work product is not subject to the privilege protections described in section 922(a) of the Public Health Service Act, 42 U.S.C. 299b–22(a), and as similarly described in proposed § 3.204(a), or to the confidentiality protection in section 922(b) of the Public Health Service Act, 42 U.S.C. 299b–22(b), and as similarly described in proposed § 3.206(a), to the extent such patient safety work product is necessary to carry out the equitable relief.

Although such disclosure is excepted from both confidentiality and privilege as to efforts to seek equitable relief, the identifiable patient safety work product remains subject to confidentiality and privilege protection in the hands of all subsequent holders and the protections apply to all subsequent potential disclosures. See section 922(d)(1) of the Public Health Service Act, 42 U.S.C. 299b–22(d)(1). Thus, even though the reporter is afforded discretion to disclose the relevant patient safety work product to seek and obtain equitable relief, all subsequent holders receiving the patient safety work product from the reporter are bound by the continued privilege and confidentiality protections.

Thus, this provision would allow the reporter seeking equitable relief from an adverse employment action to include patient safety work product in briefs and in open court. To protect the patient safety work product as much as possible in these circumstances, we could condition the disclosure of identifiable patient safety work product in these circumstances on a party's, most likely the reporter's, obtaining of a protective order in these types of proceedings. Such a protective order could take many forms that preserve the confidentiality of patient safety work product. For example, it could limit the use of the information to case preparation, but not make it evidentiary. Such an order might prohibit the disclosure of the patient safety work product in publicly accessible proceedings and in court records to prevent liability from moving to a myriad of unsuspecting parties (for example, parties in a courtroom may not know that they may be liable for civil money penalties if they share the patient safety work product they hear). We solicit comments on whether a protective order should be a condition for this disclosure, imposed by regulation, or whether instead we should require a good faith effort to obtain a protective order as a condition for this disclosure and use our enforcement discretion to consider whether to assess a penalty for anyone who cannot obtain such an order and thus breaches the statutory continued confidentiality protection of this information. See discussion below at proposed § 3.402(a).

We also address the intersection of the HIPAA Privacy Rule herein because identifiable patient safety work product may contain individually identifiable health information and be sought for disclosure under this exception from a HIPAA covered entity or that HIPAA covered entity's business associate. Under the HIPAA Privacy Rule at 45 CFR 164.512(e), when protected health information is sought to be disclosed in a judicial proceeding via subpoenas and discovery requests without a court order, the disclosing HIPAA covered entity must seek satisfactory assurances that the party requesting the information has made reasonable efforts to provide written notice to the individual who is the subject of the protected health information or to secure a qualified protective order. A protective order that meets the qualified protective order under 45 CFR 164.512(e) would be permissible under the HIPAA Privacy Rule and render a disclosure under this exception in compliance with the HIPAA Privacy Rule.

(3) Proposed § 3.206(b)(3)—Authorized by Identified Providers

Proposed § 3.206(b)(3) would establish a permitted disclosure parallel to the privilege exception at proposed § 3.204(b)(3), when each of the providers identified in the patient safety work product authorizes the disclosure in question. This provision is based on section 922(c)(1)(C) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(1)(C). In these circumstances, patient safety work product may be disclosed, not withstanding the privilege protections described in proposed § 3.204(a) or the confidentiality protections described in proposed § 3.206(a). However, patient safety work product disclosed under this exception continues to be confidential pursuant to the continued confidentiality provisions at section 922(d)(1) of the Public Health Service Act, 42 U.S.C. 299b–22(d)(1), and persons are subject to liability for further disclosures in violation of that confidentiality.

This exception applies to patient safety work product that contains identifiable provider information. Under the proposed language, each provider identified in the patient safety work product sought to be disclosed must separately authorize the disclosure. For example, if patient safety work product sought to be disclosed by an entity or person pursuant to this exception describes an incident involving three physicians, each physician would need to authorize disclosure of the patient safety work product, in order for the entity or person to disclose it. Making information regarding one provider nonidentifiable in lieu of obtaining an authorization is not sufficient.

We considered whether the rule should allow a provider to nonidentify the patient safety work product with respect to a nonauthorizing provider and disclose the patient safety work product with respect to the remaining authorizing providers. However, we rejected that approach as being impracticable. In light of the contextual nonidentification standard proposed in § 3.212, it would seem that there would be very few, if any, situations in which a nonauthorizing provider could be nonidentified without also needing to nonidentify, or nearly so, an authorizing provider in the same patient safety work product. Unless we adopt a less stringent nonidentification standard, disclosing persons can either totally nonidentify patient safety work product and disclose under proposed § 3.206(b)(5), or disclose the patient safety work product only if all identified providers in patient safety work product authorize its disclosure.

When all identified providers authorize the disclosure of patient safety work product, the Patient Safety Act permits such disclosure, but remains silent about the identification of patients or reporters in such patient safety work product. As to other persons that make patient safety work product identifiable, i.e., patients and reporters, the Patient Safety Act does not provide a separate right of authorization. However, as one of the core principles underlying the Patient Safety Act is the protection of the privacy and confidentiality concerns of certain persons in connection with specific patient safety work product (i.e., providers, patients and reporters), we encourage persons disclosing patient safety work product to exercise discretion in the scope of patient safety work product disclosed, even though neither patient nor reporter authorization is required. Disclosers are

encouraged to consider whether the disclosure of identifying information regarding patients and reporters is necessary to accomplish the particular purpose of the disclosure. As discussed below, if the disclosing entity is a HIPAA covered entity, the HIPAA Privacy Rule, including the minimum necessary standard when applicable, would apply to the disclosure of protected health information contained within the patient safety work product. We seek public comment as to whether the proposed approach is sufficient to protect the interests of reporters and patients identified in the patient safety work product permitted to be disclosed pursuant to identifiable provider authorizations. Does this approach sufficiently balance the interests of the patients and reporters and their confidentiality versus the purposes for which the providers are authorizing the disclosures?

The Patient Safety Act does not specify the form of the authorization by a provider to come within this disclosure exception or a timeframe for recordkeeping. We propose that an authorization be in writing, be signed by the authorizing provider, and give adequate notice to the provider of the nature and scope of the disclosures authorized. The content of the authorization should fairly inform the provider as to the nature and scope of the identifiable patient safety work product to be disclosed to ensure the provider is making a knowing authorization. We do not intend that each authorization identify the specific patient safety work product to be disclosed. Such a requirement would be unworkable in complex health care arrangements existing today. Rather, an authorization can be general, (e.g., referring to categories of patient safety work product) and even to patient safety work product to be created in the future, so long as the authorization can be determined to have reasonably informed the authorizing provider of the scope of the authorized disclosure. The authorization requirement also enables providers to place limits on disclosures made pursuant to this proposed exception regarding patient safety work product identifying the provider. Any disclosure must be made in accordance with the terms of the signed authorization, but we do not require that any specific terms be included, only that such terms regarding the scope of the authorized disclosure of patient safety work product be adhered to. We seek public comment on whether a more stringent standard would be prudent and workable, such as an authorization process that is disclosure specific (i.e., no future application or a one time disclosure only authorization).

We also propose that any authorization be maintained by the disclosing entity or person for a period of six years from the date of the last disclosure made in reliance on the authorization, the limit of time within which the Secretary must initiate an enforcement action. While we recognize that a prudent person disclosing patient safety work product under this disclosure will likely maintain records in order to support a claim that such disclosure was permissible, nonetheless we require a six year retention of authorizations so that, if challenged, the Secretary may examine authorizations to determine whether a disclosure was valid pursuant to this disclosure provision. While we would not be monitoring or penalizing a person for lack of maintenance of an authorization, the failure to present a valid authorization will raise significant concerns regarding the permissibility of a disclosure pursuant to this permission.

With respect to compliance with the HIPAA Privacy Rule for patient safety work product that contains individually identifiable health information, authorization by a provider pursuant to this permitted disclosure does not permit a HIPAA covered entity or such a HIPAA covered entity's business associate to release such protected health information contained in the patient safety work product under the HIPAA Privacy Rule. Therefore, either the individually identifiable health information must be de-identified or the release of the individually identifiable health information must otherwise be permitted under the HIPAA Privacy Rule. Because this disclosure does not limit the purposes for which identifiable patient safety work product may be released with the provider's authorization, a HIPAA covered entity would need to review releases on a case-by-case basis to determine if there is an applicable provision in the HIPAA Privacy Rule that would otherwise permit such disclosure.

(4) Proposed § 3.206(b)(4)—Patient Safety Activities

Section 922(c)(2)(A) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(2)(A), permits the disclosure of identifiable patient safety work product for patient safety activities. Proposed § 3.206(b)(4) permits the disclosure of identifiable patient safety work product for patient safety activities (i) by a provider to a PSO or by a PSO to that disclosing provider; or (ii) by a provider or a PSO to a contractor of the provider or PSO; or (iii) by a PSO to another PSO or to another provider that has reported to the PSO, or by a provider to another provider, provided, in both cases, certain direct identifiers are removed. Patient safety activities are the core mechanism by which providers may disclose patient safety work product to obtain external expertise from PSOs. PSOs may aggregate information from multiple providers, and communicate feedback and analyses to providers. Ultimately, it is through such communications that much of the improvement in patient safety may occur. Thus, the rule needs to facilitate the communication between a provider and one or more PSOs.

To further this essential statutory purpose, we propose to allow providers to disclose identifiable patient safety work product to PSOs; one of the ways that information can become patient safety work product is through reporting of it to a PSO. We also propose to allow PSOs to reciprocally disclose patient safety work product back to such providers for patient safety activities. This free flow of information will ensure that the statute's goals of collecting, aggregating, and analyzing patient safety event information as well as disseminating recommendations for safety and quality improvements are achieved. Such a dialogue will allow both providers and PSOs to take a shared role in the advancement of patient safety improvements.

In addition, we recognize that there may be situations where providers and PSOs want to engage contractors who are not agents to carry out patient safety activities. Thus, the proposal would allow disclosures by providers to their contractors who are not workforce members and by PSOs to their contractors who are not workforce members. Contractors may not further disclose patient safety work product, except to the entity from which they first received the information. We note that this limitation does not preclude a provider or PSO from exercising its authority under section 922(g)(4) of the Public Health Service Act, 42 U.S.C. 299b–22(g)(4), to separately delegate its power to the contractor to make other disclosures. Although we do not require a contract between a provider or PSO and its contractor, we expect that most providers and PSOs will engage in prudent practices when disclosing confidential patient safety work product for patient safety activities, (i.e., ensuring such information is narrowly used by the contractor solely for the purpose for which disclosed and

adequately protected from wrongful disclosure).

While the permission allows the necessary communication as between a single provider and its PSO, such exchanges may not be sufficient. It is possible to conceive of meaningful patient safety activities occurring between two PSOs or between a PSO and a provider that is different than the original reporting provider, or between two providers. For example, PSOs may be able to more effectively aggregate patient safety work product if such expanded sharing of information is permitted. Aggregation may help PSOs pool sufficient information to achieve contextual nonidentification, in accordance with § 3.212(a)(ii), but keep meaningful data in the information when disclosing to the network of patient safety databases contemplated in section 923 of the Public Health Service Act, 42 U.S.C. 299b–23. Providers may be able to collaborate and learn more efficiently about patient safety solutions if such sharing is permitted. At the same time, we are concerned that, without any limitation on such sharing, providers may be not only reluctant to disclose patient safety work product, but also potentially reticent to participate at all in patient safety activities, given the sensitive nature of the information, and the potential lack of certainty with respect to where the information might ultimately be disclosed.

Balancing these concerns, we are proposing that other than the reporting relationship between a provider and a PSO, PSOs be permitted to disclose patient safety work product to other PSOs or to other providers that have reported to the PSO, and providers be permitted to make disclosures to other providers, for patient safety activities, with provider and reporter identifiers in an anonymized (i.e., with certain direct identifiers removed, but not nonidentifiable under the proposed rule) or encrypted but not fully nonidentified form. For patient identifiers, the HIPAA Privacy Rule limited data set standard would apply. See 45 CFR 164.514(e). To anonymize the provider or reporter identifiers in the patient safety work product, the disclosing entity must remove the following direct identifiers of any providers and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members of such providers: (1) Names; (2) Postal address information, other than town or city, State and zip code; (3) Telephone numbers; (4) Fax numbers; (5) Electronic mail addresses; (6) Social security numbers or taxpayer identification numbers; (7) Provider or practitioner credentialing or DEA numbers; (8) National provider identification number; (9) Certificate/license numbers; (10) Web Universal Resource Locators (URLs); (11) Internet Protocol (IP) address numbers; (12) Biometric identifiers, including finger and voice prints; and (13) Full face photographic images and any comparable images. Removal of such identifiers may be absolute or may be done through encryption, provided that the disclosing entity does not disclose the key to the encryption or the mechanism for re-identification.

We have not proposed an unrestricted disclosure of identifiable patient safety work product to any person for patient safety activities. It is our understanding that disclosures to persons other than those proposed above do not need identifiable patient safety work product and that sufficient information may be communicated with nonidentifiable patient safety work product; we seek comment on this issue. Similarly, we recognize that nonidentifiable patient safety work product may have more limited usefulness due to the removal of key elements of identification; however, we have no basis for opening the patient safety activity disclosure permission further without specific examples of beneficial disclosures prohibited by our proposal.

The exchange of patient safety work product for patient safety activities permits extensive sharing among both providers and PSOs interested in improving patient safety. As patient safety work product is disclosed, however, it continues to be protected by the confidentiality provisions. The permission allows continual exchange of information without breach of confidentiality. At any time and as needed, information may be nonidentified, and the patient safety activities disclosure may be employed for this purpose.

Moreover, providers and PSOs are capable of imposing greater confidentiality requirements for the future use and disclosure of the patient safety work product through private agreements (see section 922(g)(4) of the Public Heath Service Act, 42 U.S.C. 299b–22(g)(4)). However, we note that the government would not be permitted to apply civil money penalties under this Part based on a violation of a private agreement that was not a violation of the confidentiality provisions.

Compliance With the HIPAA Privacy Rule

With respect to compliance with the HIPAA Privacy Rule, the Patient Safety Act establishes that PSOs shall be treated as business associates; and patient safety activities performed by, or on behalf of, a covered provider by a PSO are deemed health care operations as defined by the HIPAA Privacy Rule. A HIPAA covered entity is permitted to use or disclose protected health information as defined at 45 CFR 160.103 without an individual's authorization for its own health care operations and, in certain circumstances (which would include patient safety activities), for the health care operations of another HIPAA covered entity (e.g., HIPAA covered provider) under 45 CFR 164.506. To share protected health information with another HIPAA covered entity for that entity's health care operations, both HIPAA covered entities must share a patient relationship with the individual who is the subject of the protected health information and the protected health information that is shared must pertain to that relationship.

In addition, in cases where providers and PSOs share anonymized patient safety work product, providers may disclose a limited data set of patient information. Under 45 CFR 164.514(e)(3), a HIPAA covered entity may use or disclose a limited data set for the purpose of health care operations, including patient safety activities. Such disclosures, however, must be accompanied by a data use agreement, ensuring that the limited data set recipient will only use or disclose the protected health information for limited purposes. See 45 CFR 164.514(e)(4).

We seek comment regarding whether the HIPAA Privacy Rule definition for health care operations should contain a specific reference to patient safety activities conducted pursuant to this regulatory scheme. A health care provider that is a HIPAA covered entity may not disclose identifiable patient safety work product that is protected health information to a PSO unless that PSO is performing patient safety activities (as a health care operation) for that provider. Under this exception for patient safety activities, a health care provider that is a HIPAA covered entity may disclose identifiable patient safety work product that is protected health information to another provider (1) for the sending provider's patient safety activities; (2) for the patient safety activities of an organized health care arrangement (OHCA) (as defined at 45

CFR 160.103) if both the sending and receiving provider participate in the OHCA; or (3) to another provider for the receiving provider's patient safety activities if the protected health information relates to a common patient (including to determine that there is a common patient). We further seek comment regarding whether the provision permitting the disclosure of protected health information for health care operations at 45 CFR 164.506 should be modified to conform to the patient safety work product disclosures for patient safety activities set forth herein.

(5) Proposed § 3.206(b)(5)—Disclosure of Nonidentifiable Patient Safety Work Product

Proposed § 3.206(b)(5) permits the disclosure of nonidentifiable patient safety work product when the patient safety work product meets the standard for nonidentification in proposed § 3.212. This implements section 922(c)(2)(B) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(2)(B). Under proposed § 3.206(b)(5), nonidentifiable patient safety work product may be disclosed by any entity or person that holds the nonidentifiable patient safety work product without violating the confidentiality provisions. Moreover, any provider, PSO or responsible person may nonidentify patient safety work product. As described in proposed § 3.208(b)(ii), nonidentifiable patient safety work product, once disclosed, loses its privilege and confidentiality protection. Thus, it may be redisclosed by its recipient without any Patient Safety Act limitations.

Nonidentification Standard

The nonidentification standard is proposed at § 3.212. However, we will discuss that standard at this point in the preamble due to its connection with the disclosure permission for nonidentifiable patient safety work product at proposed § 3.206(b)(5). Proposed § 3.212 would establish the standard by which patient safety work product will be determined nonidentifiable. The determination of what constitutes nonidentifiable patient safety work product is important because the standard for nonidentification effectively creates the boundary between protected and unprotected patient safety work product.

Under the Patient Safety Act and this Part, identifiable patient safety work product includes information that identifies any provider or reporter or contains individually identifiable health information under the HIPAA Privacy Rule (see 45 CFR 160.103). See section 921(2) of the Public Health Service Act, 42 U.S.C. 299b–21(2). By contrast, nonidentifiable patient safety work product does not include information that permits identification of any provider, reporter or subject of individually identifiable health information. See section 921(3) of the Public Health Service Act, 42 U.S.C. 299b–21(3).

Because individually identifiable health information as defined in the HIPAA Privacy Rule is one element of identifiable patient safety work product, the de-identification standard provided in the HIPAA Privacy Rule applies with respect to the patient-identifiable information in the patient safety work product. Therefore, where patient safety work product contains individually identifiable health information, that information must be de-identified in accordance with 45 CFR 164.514(a)–(c) to qualify as nonidentifiable patient safety work product with respect to individually identifiable health information under the Patient Safety Act.

We propose that patient safety work product be contextually nonidentifiable in order to be considered nonidentifiable for the purposes of this rule. Contextual nonidentification of both providers and reporters would match the standard of de-identification in the HIPAA Privacy Rule. We are proposing two methods by which nonidentification can be accomplished which are similar to the standards for de-identification under the HIPAA Privacy Rule: (1) A statistical method of nonidentification and (2) the removal of 15 specified categories of direct identifiers of providers or reporters and of parties related to the providers and reporters, including corporate parents, subsidiaries, practice partners, employers, workforce members, or household members, and that the discloser have no actual knowledge that the remaining information, alone or in combination with other information reasonably available to the intended recipient, could be used to identify any provider or reporter (i.e., a contextual nonidentification standard).

In proposed § 3.212(a)(1), the first method for rendering patient safety work product nonidentifiable with respect to a provider or reporter, we propose that patient safety work product can be nonidentified if a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an identified provider or reporter.

We believe that this method of nonidentification may sometimes be preferable to the safeharbor method proposed in § 3.212(a)(2) discussed below and may be especially useful when aggregating data for populating the network of patient safety databases referenced in section 923 of the Public Health Service Act, 42 U.S.C. 299b–23. Under this proposal, if a statistician makes a determination as described above and documents the analysis, patient safety work product could be labeled as nonidentifiable even though it contains detailed clinical information and some potentially identifiable information such as zip codes.

In proposed § 3.212(a)(2), the second method for rendering patient safety work product nonidentifiable with respect to a provider or reporter, we outline a process as a safeharbor requiring that the disclosing entity remove a list of specific typical identifiers and have no actual knowledge that the information to be disclosed could be used, alone or in combination with other information that is reasonably available to the intended recipient, to identify the particular provider or reporter. We have limited the knowledge component to that which is known to be reasonably available to the intended recipient in order to provide data custodians with a workable knowledge standard. With the contextual nonidentification standard in place, providers will have the most confidence that their identities will not be derived from nonidentifiable information and will be more likely to participate in the program. Moreover, requiring that patient safety work product be contextually nonidentifiable is consistent with the de-identification standard for patient identities, as described above.

We recognize that the more stringent the nonidentifiable patient safety work product standard is, the more cost, burden, and risk of error in nonidentification there will be to the disclosing entity. We also acknowledge that our proposal introduces uncertainty and subjectivity into the standard, making it a harder standard to enforce. The proposed standard may require the removal of more clinical and demographic information than would be removed in the absence of the contextual nonidentification requirement, and the resulting information would likely be less useful

to a recipient. This outcome would particularly impact the network of patient safety databases of nonidentifiable patient safety work product to be established under section 923 of the Public Health Service Act, 42 U.S.C. 299b–23. In particular, the information that ultimately resides in the network may have reduced utility and a reduced capacity to contribute to the evaluation of patient safety issues.

To mitigate these concerns, this standard would work in conjunction with a separate permission for sharing identifiable patient safety work product through the patient safety activities disclosure. Disclosures as patient safety activities should enable the aggregation of sufficient patient safety work product to allow contextual nonidentification without the removal of all important specific clinical and demographic details. We invite comment on the proposed standards and approaches. For example, we are interested in knowing whether, under a contextual nonidentification standard, it is possible to have any geographical identifiers; and if so, at what level of detail (state, county, zip code). We are also interested in public comments regarding whether there are alternative approaches to standards for entities determining when health information can reasonably be considered nonidentifiable.

Re-identification

We permit a provider, PSO, or other disclosing entity or person to assign a code or other means of record identification to allow information made nonidentifiable to be re-identified by the disclosing person, provided certain conditions that further the goal of confidentiality are met regarding such code or other means of record identification. Further, a discloser may not release any key or other information that would enable a recipient to re-identify any provider or reporter or subject of individual identifiable health information. We propose to permit a re-identification mechanism to facilitate follow-up inquiries regarding, and analysis of, nonidentified patient safety work product that has been disclosed, such as from users of the network of patient safety databases when analyzing national and regional statistics. Such keys would not be for the purpose of permitting re-identification of patient safety work product obtained through the network of databases. Rather, such keys would facilitate the investigation of data anomalies reported to the network, correction of nonidentifiable records, and the potential to avoid duplicate records when richer information may be made available due to aggregation. Finally, with respect to HIPAA compliance, we note that, because nonidentified patient safety work product will, by definition, be de-identified information under the HIPAA Privacy Rule, a disclosure under § 3.206(b)(5) will not violate the HIPAA Privacy Rule.

(6) Proposed § 3.206(b)(6)—For Research

Proposed § 3.206(b)(6) describes the disclosure of identifiable patient safety work product to entities carrying out research, evaluations, or demonstration projects that are funded, certified, or otherwise sanctioned by rule or other means by the Secretary. This disclosure is not for general research. Any research for which patient safety work product is disclosed under this exception must be sanctioned by the Secretary. See section 922(c)(2)(C) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(2)(C). Research that is not sanctioned by the Secretary is insufficient to be a basis for the disclosure of patient safety work product under this exception. Further, although disclosure can be made for any research, evaluation, or demonstration project sanctioned by the Secretary, we expect that most research that may be subject to this disclosure permission will be related to the methodologies, analytic processes, and interpretation, feedback and quality improvement results from PSOs, rather than general medical, or even health services, research. Patient safety work product disclosed for research under this provision continues to be confidential and privileged.

Section 922(c)(2)(C) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(2)(C), requires that patient safety work product which identifies patients may only be released to the extent that protected health information would be disclosable for research purposes under the HIPAA Privacy Rule. Under 45 CFR 164.512(i), a HIPAA covered entity may use or disclose protected health information for research, without the individual's authorization, provided that there is a waiver (or alteration of waiver) of authorization by either an Institutional Review Board (IRB) or a Privacy Board. The IRB/Privacy Board evaluates the request against various criteria that measure the privacy risk to the individuals who are the subjects of the protected health information.[17] The HIPAA Privacy Rule only operates with respect to the identifiable health information of patients when held by a HIPAA covered entity or its business associate, and does not address the rights of individuals who may otherwise be the subject of the research.

We tentatively conclude that the language in the Patient Safety Act that applies the exception ''to the extent that disclosure of protected health information would be allowed for research purposes under the HIPAA [Privacy Rule]'' is intended to apply the HIPAA Privacy Rule research provisions at 45 CFR 164.512(i) only to HIPAA covered entities when they release identifiable patient safety work product containing protected health information for research. This interpretation would result in the HIPAA Privacy Rule research standards being preserved in their application to HIPAA covered entities without burdening non-covered entities with HIPAA compliance.

We note that our interpretation of section 922(c)(2)(C) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(2)(C), is not a bar to the disclosure of identifiable patient safety work product by entities or persons that are not HIPAA covered entities. We further note that for providers, reporters and other persons identified in patient safety work product disclosed for research purposes, the Common Rule, which is applicable to research conducted or supported by the Secretary, and the FDA human subjects protection regulations will provide appropriate protections to any natural persons who would be deemed subjects of the research.

With regard to research, the incorporation by reference of the HIPAA Privacy Rule should provide for the proper alignment of disclosures for research purposes. However, the exception under the Patient Safety Act also refers to evaluations and demonstration projects. Some of these activities may meet the definition of research under the HIPAA Privacy Rule, while other activities may not result in generalizable knowledge, but may

[17] The following are the waiver criteria at 45 CFR 164.512(i)(2)(ii):

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

a. An adequate plan to protect the identifiers from improper use and disclosure;

b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

c. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

nonetheless meet the definition of health care operations under the HIPAA Privacy Rule. Where the disclosure of protected health information for evaluations and demonstration projects are permitted as health care operations under the HIPAA Privacy Rule, HIPAA covered entities disclosing patient safety work product that includes protected health information under this exception could do so without violation of the HIPAA Privacy Rule.

(7) Proposed § 3.206(b)(7)—To the Food and Drug Administration

Section 922(c)(2)(D) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(2)(D) permits the disclosure by a provider to the FDA with respect to a product or activity regulated by the FDA. Proposed § 3.206(b)(7) permits the disclosing by providers of patient safety work product concerning products or activities regulated by the Food and Drug Administration (FDA) to the FDA or to an entity required to report to the FDA concerning the quality, safety, or effectiveness of an FDA-regulated product or activity. For example, hospitals and health care professionals may disclose patient safety work product concerning the safety of drugs, medical devices, biological products, and dietary supplements, or vaccine and medical device adverse experiences to the FDA as part of an FDA monitoring or alert system. The proposed provision also permits sharing between the FDA, entities required to report to the FDA concerning the quality, safety, or effectiveness of an FDA-regulated product or activity, and their contractors for the same purposes. Patient safety work product disclosed pursuant to this disclosure permission continues to be confidential and privileged.

The FDA has monitoring and alert systems in place to assure the safety of FDA regulated products. These systems rely heavily on voluntary reports from providers, such as hospitals and health care professionals. Most reports that hospitals and health care professionals make directly to the FDA today concerning drugs, medical devices, biological products, and dietary supplements are voluntary, although health care professionals are required to report to the FDA certain vaccine adverse experiences, and user facilities such as hospitals must report to FDA some medical device adverse experiences. Manufacturers of drugs, devices, and biological products are required to report to the FDA concerning adverse experiences, but the manufacturers themselves must rely on information provided voluntarily by product users, including hospitals and health care professionals. There are three provisions of the Patient Safety Act that are implicated for reporting to the FDA: (1) The disclosure for reporting to the FDA (section 922(c)(2)(D) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(2)(D)); (2) the clarification as to what is not patient safety work product which states that information ''collected, maintained, or developed separately, or [that] exists separately, from a [patient safety evaluation system]'' is not patient safety work product, and which, accordingly, can be reported for public health purposes (section 921(7)(B) of the Public Health Service Act, 42 U.S.C. 299b–21(7)(B)); and (3) the rule of construction which preserves required reporting to the FDA (section 922(g)(6) of the Public Health Service Act, 42 U.S.C. 299b–22(g)(6)).

The FDA disclosure provision at proposed § 3.206(b)(7) would be applicable when patient safety work product is at issue. For example, the analysis of events by the provider or PSO that constitutes patient safety work product may generate information that should be reported to the FDA because it relates to the safety or effectiveness of an FDA-regulated product or activity. The exception would allow this patient safety work product to be disclosed to the FDA. Privilege and confidentiality protections would attach to the patient safety work product disclosed when received by FDA and continue to apply to any future disclosures by the FDA.

We tentatively conclude that the statutory language concerning reporting ''to the FDA'' includes reporting by the provider to the persons or entities regulated by the FDA and that are required to report to the FDA concerning the quality, safety, or effectiveness of an FDA-regulated product or activity. We propose this interpretation to allow providers to report to manufacturers who are required to report to the FDA, such as drug manufacturers, without violating this rule. This interpretation reflects both the rule of construction which preserves required reporting to the FDA and the goals of this statute which are to improve patient safety.

We further propose at § 3.206(b)(7)(ii) that the FDA and entities required to report to the FDA may only further disclose patient safety work product for the purpose of evaluating the quality, safety, or effectiveness of that product or activity; such further disclosures are only permitted between the FDA, entities required to report to the FDA, their contractors, and disclosing providers. This permission is crucial to the effective operation of the FDA's activities and to facilitate the purpose for which the report was made initially. Thus, the FDA or a drug manufacturer receiving adverse drug event information that is patient safety work product may engage in further communications with the disclosing provider(s), for the purpose of evaluating the quality, safety, or effectiveness of the particular regulated product or activity, or may work with their contractors. Moreover, an entity regulated by the FDA may further disclose the information to the FDA; without this provision, such reporting would not meet the regulatory intent that disclosures be to the FDA and a narrow interpretation could impede the FDA's ability to effectuate improvements through the use of patient safety work product.

We recognize that there may be situations where the FDA or entities required to report to the FDA want to engage contractors who are not agents for the purpose of evaluating the quality, safety, or effectiveness of that product or activity. Thus, the proposal would allow disclosures to contractors who are not workforce members. Contractors may not further disclose patient safety work product, except to the entity from which they first received the information.

Because Congress did not expressly include disclosure to FDA-regulated entities, we seek public comment on our proposal related to this interpretation of section 922(c)(2)(D) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(2)(D). In particular, we question whether this interpretation will cause any unintended consequences to disclosing providers.

The HIPAA Privacy Rule at 45 CFR 164.512(b) permits HIPAA covered entities to disclose protected health information concerning FDA-regulated activities and products to persons responsible for collection of information about the quality, safety, and effectiveness of those FDA-regulated activities and products. Therefore, disclosures under this exception of patient safety work product containing protected health information would be permitted under the HIPAA Privacy Rule.

(8) Proposed § 3.206(b)(8)—Voluntary Disclosure to an Accrediting Body

Proposed § 3.206(b)(8) permits the voluntary disclosure of identifiable patient safety work product by a provider to an accrediting body that accredits the disclosing provider. Voluntary means not compelled, a disclosure that the provider affirmatively chose to make. Patient

safety work product disclosed pursuant to this proposed exception continues to be privileged and confidential.

Under this proposed disclosure, the identifiable patient safety work product that would be permitted to be disclosed must identify the disclosing provider, given the Patient Safety Act's explicit linkage of the disclosing provider to a body that accredits that specific provider in this permitted disclosure. We believe that the only information that would be relevant to that provider's accreditation would be information about the disclosing provider (i.e., actions or inactions of the disclosing provider), and not information about the provider's colleagues or any other accredited provider. Thus, a provider may not use this exception to disclose patient safety work product that is unrelated to the actual actions of the disclosing provider, such as information about the provider's colleagues or any other accredited individual or entity.

An issue arises concerning the identities of other providers, reporters, or patients contained within the disclosed patient safety work product. We considered whether to require the patient safety work product to be nonidentifiable as to providers other than the disclosing provider, since incidental disclosures of patient safety work product identifying other providers, especially if they were also accredited by the same accrediting institution, would not be a voluntary disclosure by those other providers. However, we do not believe that such an approach is necessary.

We understand that most providers that are accredited are large institutions, and in general their accreditors seek vast amounts of data during the accreditation process, some of which may include identifiers of practitioners who work in such institutions. We have preliminarily concluded that the disclosure of patient safety work product including practitioners in such circumstances will be harmless because, in many cases, the providers will not be accredited by the institution's accrediting body.

Even in circumstances where a non-disclosing provider identified by a provider voluntarily disclosing to an accrediting body is subject to the accrediting body, we believe the accrediting body will not use the information. First, we believe it is unlikely that a provider may have or seek to disclose patient safety work product containing information about the actions or inactions of a provider also accredited by the same accrediting body. Second, even if such a disclosure occurs, although it may not be voluntary as to the non-disclosing provider, we do not believe the accrediting body will use such information to take accrediting actions against the non-disclosing provider. We would expect that an accrediting body may ignore or give little weight to information about providers not disclosing information directly to the accrediting body. Such second hand information may be incomplete and incorrect. We anticipate that accrediting bodies would seek to obtain information about a provider's actions directly from the subject provider rather than second hand.

Furthermore, we propose to limit the accrediting body's permission to further redisclose such patient safety work product. To ensure that any patient safety work product in the hands of an accrediting body that contains provider identifiers of a provider who did not voluntarily disclose to such body, § 3.206(b)(7)(i) proposes that an accrediting body may not further disclose the patient safety work product that was originally voluntarily disclosed. As an alternative to this approach, we could, as proposed in the patient safety activities disclosure, require that information with respect to non-disclosing providers be anonymized. See preamble discussion at proposed § 3.206(b)(4). We seek comments as to whether the problem of information being disclosed non-voluntarily to an accrediting body by non-disclosing providers requires rendering such information anonymized.

The accrediting body takes the patient safety work product subject to the confidentiality protection, and would therefore be subject to civil money penalties for any re-disclosure. The patient safety work product disclosed under this permission in the hands of the accrediting body remains privileged and confidential, in accordance with the continued confidentiality provisions at proposed § 3.208. Thus, it is incumbent upon the accrediting body to handle and maintain the patient safety work product in a way that preserves its confidential status. Such safeguards may include maintaining this information separately from other accrediting information in a confidential file, if the other information is not similarly held confidential.

Additionally, the Patient Safety Act includes strong provisions limiting the disclosure of patient safety work product to accrediting bodies and limiting the actions an accrediting body may take to seek patient safety work product. Proposed § 3.206(b)(8)(ii) provides that an accrediting body may not take an accreditation action against a provider based on that provider's participation, in good faith, in the collection, reporting or development of patient safety work product. Accrediting bodies are also prohibited from requiring a provider to reveal its communications with any PSO, without regard to whether such provider actually reports information to a PSO. Thus, a provider may disclose patient safety work product to an accrediting body voluntarily, but cannot be compelled or required as a condition of accreditation to divulge patient safety work product or communications with a PSO. This subsection is based on the statutory requirements at section 922(d)(4)(B) of the Public Health Service Act, 42 U.S.C. 299b–22(d)(4)(B).

Under the HIPAA Privacy Rule, a HIPAA covered entity may disclose protected health information to an accrediting body for the HIPAA covered entity's own health care operations, provided there is a business associate agreement with the accrediting body. Such health care operations include the activity of accreditation for the HIPAA covered entity as well as the accreditation of workforce members. Thus, providers that are HIPAA covered entities or are workforce members of a HIPAA covered entity that hold the protected health information may voluntarily disclose identifiable patient safety work product containing individually identifiable health information to an accrediting body that accredits that provider, provided there is a business associate agreement between the HIPAA covered entity and the accreditation organization.

(9) Proposed § 3.206(b)(9)—Business Operations

Section 922(c)(2)(F) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(2)(F), gives the Secretary authority to designate additional disclosures as permissible exceptions to the confidentiality protection if such disclosures are necessary for business operations and are consistent with the goals of the Patient Safety Act. Any patient safety work product disclosed pursuant to a business operations exception so designated by the Secretary continues to be confidential and privileged.

We propose to allow disclosures of patient safety work product by a provider or a PSO to professionals such as attorneys and accountants for the business operations purposes of the provider or PSO. A disclosure to an attorney may be necessary when a provider is seeking outside legal advice in defending against a malpractice claim or other litigation, even though the

information would not be admissible as part of a legal proceeding. A provider might also need to disclose patient safety work product to an attorney in the case of due diligence related to a merger, sale or acquisition. Similarly, a provider may need to disclose patient safety work product to an accountant who is auditing the books and records of providers and PSOs. In order to ensure that such routine business operations are possible, we propose to allow disclosures by providers and PSOs for business operations to attorneys, accountants, and other professionals. Professionals such as those identified are usually bound by professional ethics to maintain the confidences of their clients. Such contractors may not further disclose patient safety work product, except to the entity from which it received the information. We note that this limitation does not preclude a provider or PSO from exercising its authority under section 922(g)(4) of the Public Health Service Act, 42 U.S.C. 299b–22(g)(4), to separately delegate its power to the contractor to make other disclosures.

We note that if a provider or PSO were to disclose relevant patient safety work product to such professionals, we would rely upon the professional's legal and ethical constraints not to disclose the information for any unauthorized purpose. Our presumption is that professionals are generally subject to a set of governing rules. Nonetheless, we expect that providers and PSOs who disclose privileged and confidential information to attorneys, accountants or other ethically bound professionals for business purposes will engage in the prudent practice of ensuring such information is narrowly used by the contractor solely for the purpose for which it was disclosed and adequately protected from wrongful disclosure.

Because patient safety work product is specialized and highly confidential information, we have not conceived of any other third parties to whom it would be appropriate to disclose patient safety work product as a business operations disclosure. Because we are not regulating uses, any business operations need within the entity could occur unimpeded. Although we considered whether to adopt an exception for activities in the operation of a patient safety evaluation system, we believe these activities are within the definition of patient safety activities and, thus, within the confidentiality exception proposed at § 3.206(b)(4). We seek public comment regarding whether there are any other consultants or contractors to whom a business operations disclosure should also be permitted, or whether there are any additional exceptions for the Secretary's consideration under this authority.

Under the HIPAA Privacy Rule, at 45 CFR 164.506, HIPAA covered entities are permitted to disclose protected health information for the HIPAA covered entity's own health care operations. ''Health care operations'' are certain activities of a HIPAA covered entity that are necessary to run its business and to support the core functions of treatment and payment, including ''conducting or arranging for medical review, legal services, and auditing functions * * *.'' 45 CFR 164.501. Thus, a business operation designation by the Secretary that enables a HIPAA covered entity to disclose patient safety work product containing protected health information to professionals is permissible as health care operations disclosures under the HIPAA Privacy Rule. Generally such professionals would fall within the definition of business associate at 45 CFR 160.103 and would require a business associate agreement.

The Secretary's Business Operations Exception Designation Authority

Section 922(c)(2)(F) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(2)(F), gives the Secretary broad authority to designate additional exceptions that are necessary for business operations and are consistent with the goals of the Patient Safety Act. At this point, we plan to designate additional exceptions only through regulation. Although the Patient Safety Act establishes that other means are available for adoption by the Secretary, which we interpret as including the publication of letters, notice within the **Federal Register** or publication on the Department Web site, we believe these methods may not provide for sufficient opportunity for public comment or transparency in the development of other business operations exceptions. Moreover, because an impermissible disclosure that violates a business operations exception can result in a civil money penalty, we believe it is important that any proposed business operations exception be implemented in a way that is unquestionably binding on both the public and the Department. We invite public comments with respect to whether the Secretary should incorporate or preserve other mechanisms for the adoption of business operations exceptions, given that we cannot anticipate all potential business operations needs at this time.

(10) Proposed § 3.206(b)(10)—Disclosure to Law Enforcement

Proposed § 3.206(b)(10) permits the disclosure of identifiable patient safety work product to law enforcement authorities, so long as the person making the disclosure believes—and that belief is reasonable under the circumstances—that the patient safety work product disclosed relates to a crime and is necessary for criminal law enforcement purposes. Under proposed § 3.208, the disclosed patient safety work product would continue to be privileged and confidential.

We view this exception as permitting, for example, a disclosure by a whistleblower who would initiate the disclosure to law enforcement. The focus of this exception is the state of mind of the subject discloser. In making a disclosure, the discloser must reasonably believe that the event constitutes a crime and that the patient safety work product disclosed is necessary for criminal law enforcement purposes. The discloser need not be correct in these determinations, but his beliefs must be objectively reasonable. This standard provides some constraint on the discloser, and further protects against a release merely in response to a request by law enforcement.

Patient safety work product received by law enforcement under this exception continues to be confidential and privileged. The law enforcement entity receiving the patient safety work product may use the patient safety work product to pursue any law enforcement purposes; however, because the patient safety work product disclosed to law enforcement entities under the Patient Safety Act and proposed § 3.206(b)(10) remains privileged and confidential, the law enforcement entity can only disclose such patient safety work product—including in a court proceeding—as permitted by this proposed rule.

We further propose that a law enforcement entity be permitted to redisclose the patient safety work product it receives under this exception to other law enforcement entities as needed for law enforcement activities related to the event that gave rise to the disclosure. We seek comment regarding whether these provisions allow for legitimate law enforcement needs, while ensuring appropriate protections.

We note that disclosure pursuant to this exception does not except patient safety work product from the privilege protection. Thus, patient safety work product cannot be subpoenaed, ordered, or entered into evidence in a criminal or civil proceeding through this exception;

nor should a discloser rely solely on a law enforcement agent's statement that such information is necessary for law enforcement purposes. As already discussed, the Patient Safety Act framework permits an exception from privilege protection or law enforcement compulsion only in very narrow circumstances (see above privilege exception discussion). Under section 922(c)(1)(A) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(1)(A), patient safety work product may be disclosed for use in a criminal proceeding, but only after a judge has determined by means of an *in camera* review that the patient safety work product is material to a criminal proceeding and not reasonably available from any other source. Even after its use in such a criminal proceeding, and the lifting of the confidentiality protections with respect to such patient safety work product, the privilege protection continues. In light of the strict privilege protections for this information, we do not interpret this law enforcement disclosure exception as allowing the disclosure of patient safety work product based on a less compelling request by law enforcement for its release. The decision as to whether a discloser reasonably believes that the patient safety work product is necessary for a law enforcement purpose is the discloser's decision alone, provided that the decision is reasonable.

While the HIPAA Privacy Rule permits disclosures by HIPAA covered entities to law enforcement under a variety of circumstances, few align well with the proposed interpretation of this exception as being limited to disclosures to law enforcement initiated by the HIPAA covered entity. Although there is a very narrow set of HIPAA Privacy Rule permissions under which a HIPAA covered entity as a holder of patient safety work product would be allowed to release patient safety work product that contains protected health information to law enforcement, we note that a HIPAA covered entity would be permitted to de-identify the protected health information, in which case only the Patient Safety Act would apply to the disclosure of the patient safety work product. If the protected health information is needed by law enforcement, the HIPAA Privacy Rule has standards that permit the release of protected health information in response to certain law enforcement processes. If such information is not patient safety work product, it would not be subject to the privilege protections of the Patient Safety Act.

(C) Proposed § 3.206(c)—Safe Harbor

Proposed § 3.206(c) is based on section 922(c)(2)(H) of the Public Health Service Act, 42 U.S.C. 299b–22(c)(2)(H). This provision permits the disclosure of identifiable patient safety work product when that information does not include oral or written materials that either contain an assessment of the quality of care of an identifiable provider or describe or pertain to the actions or failure to act of an identifiable provider. The use of this exception is limited to persons other than PSOs. This provision essentially prohibits the disclosure of a subject provider's identity with information, whether oral or written, that: (1) Assesses that provider's quality of care; or (2) identifies specific acts attributable to such provider. Thus, a permissible disclosure may include a provider's identity, so long as no ''quality information'' about the subject provider is also disclosed and so long as it does not describe or pertain to an action or failure to act by the subject provider.

We propose that the provider identity element under this exception means the identity of any provider that is a subject of the patient safety work product. In other words, if the patient safety work product does not contain quality information about a particular provider or describe or pertain to any actions or failures to act by the provider, such provider could be identifiable within the patient safety work product disclosed pursuant to this exception. For example, if a nurse reports a patient safety event, but was not otherwise involved in the occurrence of that event, the nurse could be named in the disclosure. Providers that cannot be identified are those about whom the patient safety work product assesses the quality of care or describes or pertains to actions or failures to act of that provider. We propose that the threshold for identification of a provider will be determined in accordance with the nonidentification standard set forth in proposed § 3.210. Thus, confidential patient safety work product disclosed under this exception may identify providers, reporters or patients so long as the provider(s) that are the subject of the actions described are nonidentified.

In general, the determination with respect to the content of quality information is straightforward. We also interpret quality information to include the fact that patient safety work product exists, without the specifics of the patient safety event at issue. For example, if a provider employee discloses to a friend that a particular surgeon had an incident reported to the PSO, without actually describing this incident, the fact that the surgeon was associated with patient safety work product would be a prohibited disclosure.

This is the only exception that defines prohibited conduct, rather than permitted conduct. We recognize that institutional providers, even practitioners offices, are communities unto themselves. We preliminarily interpret this exception as creating a narrow safe harbor for disclosures, possibly inadvertent, which may occur by a provider or other responsible person, when the patient safety work product does not reveal a link between a subject provider and the provider's quality of care or an action or failure to act by that subject provider. By proposing this provision as a safe harbor, we seek to have it available to mitigate harmless errors, rather than as a disclosure permission that may render all other disclosure permissions practically meaningless.

Under the HIPAA Privacy Rule, HIPAA covered entities are broadly permitted to disclose protected health information for the HIPAA covered entity's treatment, payment or health care operations. Otherwise, specific standards are described that limit the use and disclosure of protected health information. If such disclosure is made by a HIPAA covered entity, it is possible that the disclosure of protected health information would be permissible as a health care operation, or as incidental to another permitted disclosure. Nevertheless, examination of whether a HIPAA Privacy Rule standard has been violated will need to be made on a case-by-case basis.

(D) Proposed § 3.206(d)—Implementation and Enforcement of the Patient Safety Act

Proposed § 3.206(d) permits the disclosure of relevant patient safety work product to or by the Secretary as needed for investigating or determining compliance with this Part or for enforcement of the confidentiality provisions of this Subpart or in making or supporting PSO certification or listing decisions under the Patient Safety Act and Subpart B of this regulation. This disclosure parallels the privilege exception under proposed § 3.204(c). Patient safety work product disclosed under this exception remains confidential. This exception does not limit the ability of the Secretary to disclose patient safety work product in accordance with the exceptions under proposed § 3.206(b) or this Part. Rather, this proposed section provides a specific permission pursuant to which

patient safety work product may be disclosed to the Secretary and the Secretary may further use such disclosed patient safety work product for compliance and enforcement purposes.

We propose to permit a disclosure of patient safety work product in order to allow the Secretary to obtain such information as is needed to implement and enforce this program, both for the purposes of enforcing the confidentiality of patient safety work product and for the oversight of PSOs. Enforcement of the confidentiality provisions includes the imposition of civil money penalties and adherence to the prohibition against imposing a civil money penalty for a single act that violates both the Patient Safety Act and the HIPAA Privacy Rule. This exception ensures that there will not be a conflict between the confidentiality obligations of a holder of patient safety work product and other provisions that allow the Secretary access to protected information and/or require disclosure to the Secretary for enforcement purposes. See proposed §§ 3.110, 3.210, and 3.310. Although the statute does not explicitly address this disclosure, we believe that the authority to disclose to the Secretary for these purposes is inherent in the statute, and that this disclosure is permitted and necessary to meaningfully exercise our authority to enforce against breaches of confidentiality as well as to ensure that PSOs meet their certification attestations if needed. Proposed § 3.312(c) discusses the limitations on what the Secretary may do with any patient safety work product obtained pursuant to an investigation or compliance review regarding an alleged impermissible disclosure.

This proposed provision would permit the disclosure of patient safety work product to the Secretary or disclosure by the Secretary so long as such disclosure is limited to the purpose of implementation and enforcement of these proposed regulations. Such disclosure would include the introduction of patient safety work product into proceedings before ALJs or the Board under proposed Subpart D by the Secretary, as well as the disclosure during investigations by the Secretary, or activities in reviewing PSO certifications by AHRQ. Disclosures of patient safety work product made to the Board or other parts of the Department that are received by workforce members, such as contractors operating electronic web portals or mail sorting and paper scanning services, would be permitted as a disclosure to the Secretary under this proposed provision. This provision would also permit the Board to disclose any patient safety work product in order to properly review determinations or to provide records for court review.

We believe strongly in the protection of patient safety work product as provided in the Patient Safety Act and the proposed regulations, and seek to minimize the risk of improper disclosure of patient safety work product by using and disclosing patient safety work product only in limited and necessary circumstances. With respect to disclosures to an ALJ or the Board, we note that the Board has numerous administrative, technical and physical safeguards available to protect sensitive information. For example, the Board has the authority to: Enter protective orders; hold closed hearings; redact records; anonymize names of cases and parties prior to publishing opinions; and put records under seal. It routinely maintains a controlled environment; trains staff about proper handling of confidential information; flags confidential information in records prior to archiving cases and shreds copies of case files, etc. Most importantly, understanding that any patient safety work product that is used in an enforcement proceeding is sensitive, the Board would seek to include only information in an opinion that is necessary to the decision, and omit any extraneous sensitive information that is not needed for its judgments.

This proposed provision also requires that patient safety work product disclosed to or by the Secretary must be necessary for the purpose for which the disclosure is made. We intend that any disclosure made pursuant to this proposed provision be limited in the amount of patient safety work product disclosed to accomplish the purpose of implementation, compliance, and enforcement. We discuss our anticipated uses and protections further in proposed Subpart D.

(E) Proposed § 3.206(e)—No Limitation on Authority To Limit or Delegate Disclosure or Use

Proposed § 3.206(e) reflects the Patient Safety Act's rule of construction in section 922(g)(4) of the Public Health Service Act, 42 U.S.C. 299b–22(g)(4), establishing that a person holding patient safety work product may enter into a contract that requires greater confidentiality protections or may delegate its authority to make a disclosure in accordance with this Subpart. For example, a provider may delegate its permission (which it may have as a provider) to disclose to the FDA under proposed § 3.206(b)(7) to a PSO through a contractual arrangement. In such a case, the PSO would be acting on behalf of the provider in making disclosures to the FDA. Without the delegated permission, it would, in this scenario, be impermissible for the PSO to disclose identifiable patient safety work product to the FDA, and a PSO that made such a disclosure could be subject to a civil money penalty. However, if a delegation of disclosing authority exists, the delegating person would be responsible for the disclosures of the delegee. Thus, in the example above, if the PSO made an impermissible disclosure, the delegating provider could be liable under the principle of principal liability for the acts of its agent. The PSO making the disclosure could also be liable. See discussion in proposed § 3.402(b). Neither the statute nor the proposed rule limits the authority of a provider to place limitations on disclosures or uses. For example, a provider may require that a PSO remove all employee names prior to disclosing any patient safety work product despite such disclosure being permissible under this Subpart with the names included.

3. Proposed § 3.208—Continued Protection of Patient Safety Work Product

Proposed § 3.208 provides that the privilege and confidentiality protections continue to apply to patient safety work product when disclosed and describes the narrow circumstances when the protections terminate. Generally, when identifiable patient safety work product is disclosed, whether pursuant to a permitted exception to privilege and/or confidentiality or disclosed impermissibly, that patient safety work product continues to be privileged and confidential. Any person receiving such patient safety work product receives that patient safety work product pursuant to the privilege and confidentiality protections. The receiving person holds the patient safety work product subject to these protections and is generally bound by the same limitations on disclosure and the potential civil money penalty liability if he or she discloses the patient safety work product in a manner that warrants imposition of a civil money penalty under proposed Subpart D.

An example would be if identifiable patient safety work product is disclosed to a provider's employee for patient safety activities, the identifiable patient safety work product disclosed to the employee would be confidential and the employee would be subject to civil money penalty liability for any knowing

or reckless disclosure of the patient safety work product in identifiable form not permitted by the exceptions. Similarly, if confidential patient safety work product is received impermissibly, such as by an unauthorized computer access (*i.e.*, hacker), the impermissible disclosure, even when unintentional, does not terminate the confidentiality. Thus, the hacker may be subject to civil money penalty liability for impermissible disclosures of that information.

We do not require that notification of the privilege and confidentiality of patient safety work product be made with each disclosure. We also note that the Secretary does not have authority to impose a civil money penalty for an impermissible breach of the privilege protection. Rather, any breach of privilege, permissible or not, would encompass a disclosure and concurrent breach of confidentiality, subject to penalty under the CMP provisions of the Patient Safety Act and this proposed rule, unless a confidentiality exception applied. See the discussion above of confidentiality protections at proposed § 3.206 and the discussion of the enforcement provisions at proposed Subpart D.

Nor do we require notification of either the confidentiality of patient safety work product or the fact that patient safety work product is being disclosed. The Secretary's authority to impose a civil money penalty is not dependent upon whether the disclosing entity or person knows that the information being disclosed is patient safety work product or whether patient safety work product is confidential (see discussion under proposed Subpart D). Thus, we do not require that the disclosure of patient safety work product be accompanied by a notice as to either the fact that the information disclosed is patient safety work product or that it is confidential. Labeling does not make information protected patient safety work product, and the failure to label patient safety work product does not remove the protection. However, we do believe that such a notification would be beneficial to the recipient to alert such recipient to the fact that the information received should be held in a confidential manner and that knowing or reckless disclosure in violation of the confidentiality protection may subject a discloser to civil money penalties. Labeling patient safety work product may also make it easier for the provider to establish that such information is privileged patient safety work product. Also, a notification may also be prudent management for providers, PSOs, and responsible persons who could be subject to liability under agency principles for actions of disclosing agents. Moreover, such a notification policy may serve as a mitigating factor under the factors outlined under proposed Subpart D. Similarly, labeling of patient safety work product may be a good practice for the internal management of information by an entity that holds protected patient safety work product.

There are two exceptions to the continued protection of patient safety work product which terminate either the confidentiality or both the privilege and confidentiality under section 922(d)(2) of the Public Health Service Act, 42 U.S.C. 299b–22(d)(2). The first exception to continued protection is an exception to continued confidentiality when patient safety work product is disclosed for use in a criminal proceeding, pursuant to proposed §§ 3.204(b)(1) and 3.206(b)(1). Proposed § 3.204(b)(1) is an exception to privilege for the particular proceeding at issue and does not permit the use of such patient safety work product in other proceedings or otherwise remove the privilege protection afforded such information. Thus, in the case of a criminal proceeding disclosure, the privilege continues even though the confidentiality terminates. In other words, when a court makes an *in camera* determination that patient safety work product can be entered into a criminal proceeding, that information remains privileged for any future proceedings, but is no longer confidential and may be further disclosed without restriction.

The second exception to continued protection is when patient safety work product is disclosed in nonidentifiable form, pursuant to proposed §§ 3.204(b)(4) and 3.206(b)(5). Under both of these exceptions, the patient safety work product disclosed is no longer confidential, and may be further disclosed without restriction. The termination of the continued protections is based on section 922(d)(2) of the Public Health Service Act, 42 U.S.C. 299b–22(d)(2).

4. Proposed § 3.210—Required Disclosure of Patient Safety Work Product to the Secretary

We are proposing in § 3.210 that providers, PSOs, and other persons that hold patient safety work product be required to disclose such patient safety work product to the Secretary upon a determination by the Secretary that such patient safety work product is needed for the investigation and enforcement activities related to this Part, or is needed in seeking and imposing civil money penalties. Such patient safety work product disclosed to the Secretary will be excepted from privilege and confidentiality protections insofar as the Secretary has a need to use such patient safety work product for the above purposes which include: accepting, conditioning, or revoking acceptance of PSO certification or in supporting such actions. See proposed § 3.206(d).

5. Proposed § 3.212—Nonidentification of Patient Safety Work Product

Proposed § 3.210 establishes the standard by which patient safety work product will be determined nonidentifiable. For the ease of the reader, we have discussed this standard within the context of proposed § 3.206(b)(5), the confidentiality disclosure exception for nonidentifiable patient safety work product.

D. Subpart D—Enforcement Program

The authority of the Secretary to enforce the confidentiality provisions of the Patient Safety Act is intended to deter impermissible disclosures of patient safety work product. Proposed Subpart D would establish a framework to enable the Secretary to monitor and ensure compliance with this Part, procedures for imposing a civil money penalty for breach of confidentiality, and procedures for a hearing contesting a civil money penalty.

The proposed enforcement program has been designed to provide maximum flexibility to the Secretary in addressing violations of the confidentiality provisions to encourage participation in patient safety activities and achieve the goals of the Patient Safety Act while safeguarding the confidentiality and protected nature of patient safety work product under the Patient Safety Act and this part. Failures to maintain confidentiality may be serious, deleterious and broad-ranging, and, if unpunished, may discourage participation by providers in the PSO voluntary reporting system. The Secretary's enforcement authority will be exercised commensurately to respond to the nature of any such failure and the resulting harm from such failures. The proposed regulations seek to provide the Secretary with reasonable discretion, particularly in areas where the exercise of judgment is called for by the statute or proposed rules, and to avoid being overly prescriptive in areas and causing unintended adverse effects where it would be helpful to gain experience with the practical impact of the proposed rules.

The provisions of section 1128A of the Social Security Act, 42 U.S.C. 1320a–7a, apply to the imposition of a

civil money penalty under section 922(f) of the Public Health Service Act, 42 U.S.C. 299b–22(f), ''in the same manner as'' they apply to the imposition of civil money penalties under section 1128A itself. Section 1128A(*l*) of the Social Security Act, 42 U.S.C. 1320a–7a(*l*), provides that a principal is liable for penalties for the actions of its agents acting within the scope of their agency. Therefore, a provider or PSO will be responsible for the actions of a workforce member when such member discloses patient safety work product in violation of the confidentiality provisions while acting within the scope of the member's agency relationship.

Proposed §§ 3.304 through 3.314 are designed to enable the Secretary to assist with, monitor, and investigate alleged failures with respect to compliance with the confidentiality provisions. Proposed §§ 3.304 through 3.314 would establish the processes and procedures for the Secretary to provide technical assistance with compliance, for filing complaints with the Secretary, and for investigations and compliance reviews performed by the Secretary. Proposed §§ 3.402 through 3.426 would provide the legal basis for imposing a civil money penalty, determining the amount of a civil money penalty, implementing the prohibition on the imposition of a civil money penalty under both HIPAA and the Patient Safety Act, and issuing a notice of proposed determination to impose a civil money penalty and establishing the process that would be relevant subsequent to the issuance of such a notice, whether or not a hearing follows the issuance of the notice of proposed determination. These sections also would contain provisions on the statute of limitations, authority to settle, collection of any penalty imposed for violation of the confidentiality provisions, and public notice of the imposition of such penalties. Finally, proposed § 3.504 addresses the administrative hearing phase of the enforcement process, including provisions for appellate review within HHS of a hearing decision and burden of proof in such proceedings.

Generally, proposed Subpart D is based on the HIPAA Enforcement Rule, 45 CFR Part 160, Subparts C, D and E. We have closely followed the HIPAA Enforcement Rule for several reasons. First, because civil money penalties under both the HIPAA Enforcement Rule and Patient Safety Act are based on section 1128A of the Social Security Act, 42 U.S.C. 1320a–7a, we believe there is benefit in maintaining a common approach to enforcement and appeals of such civil money penalty determinations. Second, we believe that these procedures set forth in the HIPAA Enforcement Rule, which in turn are based on the procedures established by the OIG, work and satisfactorily address issues raised and addressed in prior rulemakings by the Department and the OIG. We do not reiterate those concerns, or their resolutions, here, but they have informed our decision making on these proposed rules.

Proposed §§ 3.504(b)–(d), (f)–(g), (i)–(k), (m), (n), (t), (w) and (x) of the proposed rule are unchanged from, or incorporate the provisions of, the HIPAA Enforcement Rule. For a full discussion of the basis for these proposed sections, please refer to the proposed and final HIPAA Enforcement Rule, published on April 18, 2005, at 70 FR 20224 (proposed) and on February 16, 2006, at 71 FR 8390 (final). Although the preamble discussion of the HIPAA Enforcement Rule pertains to the HIPAA Administrative Simplification provisions, HIPAA covered entities, and protected health information under HIPAA, we believe the same interpretations and analyses are applicable to the Patient Safety Act confidentiality provisions, providers, PSOs, and responsible persons, and patient safety work product.

Proposed §§ 3.424 and 3.504(a), (e), (h), (l), (o)–(s), (u) and (v) of the proposed rule also are based on, or incorporate, the HIPAA Enforcement Rule, but include technical changes made in order to adapt these provisions to the Patient Safety Act confidentiality provisions. We discuss these technical changes below but refer to the proposed and final HIPAA Enforcement Rule for a substantive discussion of these proposed sections.

For the above proposed sections, while we have chosen not to repeat our discussion of the rationale for these regulations, we invite comments regarding whether any further substantive or technical changes are needed to adapt these provisions to the Patient Safety Act confidentiality provisions.

The remaining sections in Subpart D of the proposed rule reprint HIPAA Enforcement Rule provisions in their entirety or constitute substantive changes from the analogous provisions of the HIPAA Enforcement Rule. We discuss these proposed sections in full below.

1. Proposed § 3.304—Principles for Achieving Compliance

Proposed § 3.304(a) would establish the principle that the Secretary will seek the cooperation of providers, PSOs, and responsible persons in maintaining and preserving the confidentiality of patient safety work product, relying on the civil money penalty authority when appropriate to remediate violations. Proposed § 3.304(b) provides that the Secretary may provide technical assistance to providers, PSOs, and responsible persons to help them comply with the confidentiality provisions.

We will seek to achieve compliance through technical assistance and outreach so that providers, PSOs, and responsible persons that hold patient safety work product may better understand the requirements of the confidentiality provisions and, thus, may voluntarily comply by preventing breaches. However, we believe that the types of events that are likely to trigger complaints are actual breaches of confidentiality which will need remedial action (such events cannot be mitigated through preventive measures alone). Given the existing framework of peer review systems and other similar processes, we believe that most providers and patient safety experts already have well-established mechanisms for using sensitive information while respecting its confidentiality. Moreover, such persons will have incentives to maintain the confidentiality of patient safety work product each such person possesses in the future. Thus, while there may be situations where an issue may be resolved through technical assistance and corrective action, we anticipate that the resolution of complaints of breaches of confidentiality may warrant imposition of a civil money penalty to deter future non-compliance and similar violations. This Subpart preserves the discretion of the Secretary to enforce confidentiality in the manner that best fits the situation.

The Secretary will exercise discretion in developing a technical assistance program that may include the provision of written material when appropriate to assist persons in achieving compliance. We encourage persons to share ''best practices'' for the confidential utilization of patient safety work product. However, the absence of technical assistance or guidance may not be raised as a defense to civil money penalty liability.

2. Proposed § 3.306—Complaints to the Secretary

We are proposing in § 3.306 that any person may file a complaint with the Secretary if the person believes that a provider, PSO or responsible person has disclosed patient safety work product in violation of the confidentiality

provisions. A complaint-driven process would provide helpful information about the handling and disclosure of patient safety work product and could serve to identify particularly troublesome compliance problems on an early basis.

The procedures proposed in this section are modeled on those used for the HIPAA Enforcement Rule. We would require: complaints to be in writing; complainants to identify the person(s), and describe the acts, alleged to be out of compliance; and that the complainant file such complaint within 180 days of when the complainant knew or should have known that the act complained of occurred, unless this time limit is waived by the Secretary for good cause shown. We have tried to keep the requirements for filing complaints as minimal as possible to facilitate use of this process. The Secretary would also attempt to keep the identity of complainants confidential, if possible. However, we recognize that it could be necessary to disclose the identity of a complainant in order to investigate the substance of the complaint, and the rules proposed below would permit such disclosures.

For the same reason that the HIPAA Enforcement Rule adopted the ''known or should have known'' standard for filing a complaint, we require that complaints be filed within 180 days of when the complainant knew or should have known that the violation complained of occurred unless this time limit is waived by the Secretary for good cause shown. We believe that an investigation of a complaint is likely to be most effective if persons can be interviewed and documents reviewed as close to the time of the alleged violation as possible. Requiring that complaints generally be filed within a certain period of time increases the likelihood that the Secretary will be able to obtain necessary and reliable information in order to investigate allegations. Moreover, we are taking this approach in order to encourage complainants to file complaints as soon as possible. By receiving complaints in a timely fashion, we can, if such complaints prove valid, reduce the harm caused by the violation.

In most cases, we expect that the providers, PSOs, responsible persons, and/or their employees will be aware of disclosures of patient safety work product. Nevertheless, other persons may become aware of the wrongful disclosure of patient safety work product as well. For these reasons, we do not limit who may file a complaint. We will accept complaints alleging violations from any person.

Once a complaint is received, the Secretary will notify the provider, PSO, or responsible person(s) against whom the complaint has been filed (i.e., the respondent), investigate and seek resolution to any violations based on the circumstances of the violation, in accordance with the principles for achieving compliance. In enforcing the confidentiality provisions of the Patient Safety Act, the Secretary will generally inform the respondent of the nature of any complaints received against the respondent. The Secretary will also generally afford the entity an opportunity to share information with the Secretary that may result in an early resolution.

3. Proposed § 3.308—Compliance Reviews

We are proposing in § 3.308 that the Secretary could conduct compliance reviews to determine whether a provider, PSO, or responsible person is in compliance. A compliance review could be based on information indicating a possible violation of the confidentiality provisions even though a formal complaint has not been filed. As is the case with a complaint investigation, a compliance review may examine the policies, practices or procedures of a respondent and may result in voluntary compliance or in a finding of a violation or no violation finding.

We believe the Secretary's ability to conduct compliance reviews should be flexible and unobstructed by limitations or required links to ongoing investigations. We do not establish any affirmative criteria for the conduct of a compliance review. Compliance reviews may be undertaken without regard to ongoing investigations or prior conduct. We recognize that cooperating with compliance reviews may create some burden and expense. However, the Secretary needs to maintain the flexibility to conduct whatever reviews are necessary to ensure compliance with the rule.

We note that, at least in the short term, HHS will be taking a case-based, complaint-driven approach to investigations and enforcement, rather than focusing resources on compliance reviews unrelated to any information or allegations of confidentiality violations.

4. Proposed § 3.310—Responsibilities of Respondents

Proposed § 3.310 establishes certain obligations for respondents that would be necessary to enable the Secretary to carry out the statutory role to determine their compliance with the requirements of the confidentiality provisions. Respondents would be required to maintain records as proposed in this proposed rule, participate as required in investigations and compliance reviews, and provide information to the Secretary upon demand. Respondents would also be required to disclose patient safety work product to the Secretary for investigations and compliance activities. We interpret the enforcement provision at section 922(f) of the Patient Safety Act, 42 U.S.C. 299b–22(f), to allow for such disclosure to the Secretary for the purpose of enforcing the confidentiality provisions.

Proposed § 3.310(b) would require cooperation by respondents with investigations as well as compliance reviews.

Proposed § 3.310(c) would provide that the Secretary must be provided access to a respondent's facilities, books, records, accounts, and other sources of information, including patient safety work product. Ordinarily, the Secretary will provide notice requesting access during normal business hours. However, if exigent circumstances exist, such as where documents might be hidden or destroyed, the Secretary may require access at any time and without notice. The Secretary will consider alternative approaches, such as subpoenas or search warrants, in seeking information from respondents that are not providers, PSOs, or a member of their workforce.

5. Proposed § 3.312—Secretarial Action Regarding Complaints and Compliance Reviews

Proposed § 3.312(a) provides that, if a complaint investigation or compliance review indicates noncompliance, the Secretary may attempt to resolve the matter by informal means. If the Secretary determines that the matter cannot be resolved by informal means, the Secretary will issue findings to the respondent and, if applicable, the complainant.

Proposed § 3.312(a)(1) provides that, where noncompliance is indicated, the Secretary could seek to reach a resolution of the matter satisfactory to the Secretary by informal means. Informal means would include demonstrated compliance or a completed corrective action plan or other agreement. Under this provision, entering into a corrective action plan or other agreement would not, in and of itself, resolve the noncompliance; rather, the full performance by the respondent of its obligations under the corrective action plan or other agreement would be necessary to resolve the noncompliance.

Proposed §§ 3.312(a)(2) and (3) address what notifications would be provided by the Secretary where noncompliance is indicated, based on an investigation or compliance review. Notification under these paragraphs would not be required where the only contacts made were with the complainant to determine whether the complaint warrants investigation. Section 3.312(a)(2) proposes written notice to the respondent and, if the matter arose from a complaint, the complainant, where the matter is resolved by informal means. If the matter is not resolved by informal means, proposed § 3.312(a)(3)(i) would require the Secretary to so inform the respondent and provide the respondent 30 days in which to raise any mitigating factors the Secretary should consider in imposing a civil money penalty. Section 3.312(a)(3)(ii) proposes that, where a matter is not resolved by informal means and the Secretary decides that imposition of a civil money penalty is warranted based upon a response from the respondent or expiration of the 30 day response time limit, the formal finding would be contained in the notice of proposed determination issued under proposed § 3.420.

Proposed § 3.312(b) provides that, if the Secretary finds, after an investigation or compliance review, no further action is warranted, the Secretary will so inform the respondent and, if the matter arose from a complaint, the complainant. This section does not apply where no investigation or compliance review has been initiated, such as where a complaint has been dismissed due to lack of jurisdiction.

Proposed § 3.312(c) addresses how the Secretary will handle information obtained during the course of an investigation or compliance review. Under proposed § 3.312(c)(1), identifiable patient safety work product obtained by the Secretary in connection with an investigation or compliance review under this Part remains subject to the privilege and confidentiality protections and will not be disclosed except in accordance with proposed § 3.206(d), if necessary for ascertaining or enforcing compliance with this part, or as permitted by this Part or the Patient Safety Act. In other words, the Secretary, as with any other entity or person, would receive patient safety work product subject to the confidentiality and privilege requirements and protections. The proposed rule strikes a balance between these protections and enforcement, providing that the Secretary would not disclose such patient safety work product, except as may be necessary to enable the Secretary to ascertain compliance with this Part, in enforcement proceedings, or as otherwise permitted by this Part. We note that, pursuant to section 922(g)(3) of the Public Health Service Act, 42 U.S.C. 299b–22(g)(3), as added by the Patient Safety Act, the Patient Safety Act does not affect the implementation of the HIPAA confidentiality regulations (known as the HIPAA Privacy Rule). Accordingly, we propose that the Secretary may use patient safety work product obtained in connection with an investigation hereunder to enforce the HIPAA confidentiality regulations.

Proposed § 3.312(c)(2) provides that, except for patient safety work product, testimony and other evidence obtained in connection with an investigation or compliance review may be used by HHS in any of its activities and may be used or offered into evidence in any administrative or judicial proceeding. Such information would include that which is obtained from investigational subpoenas and inquiries under proposed § 3.314. The Department generally seeks to protect the privacy of individuals to the fullest extent possible, while permitting the exchange of records required to fulfill its administrative and programmatic responsibilities. The Freedom of Information Act, 5 U.S.C. 552, and the HHS implementing regulation, 45 CFR Part 5, provide substantial protection for records about individuals where disclosure would constitute an unwarranted invasion of their personal privacy. Moreover, in enforcing the Patient Safety Act and its implementing regulations, OCR plans to continue its current practice of protecting its complaint files from disclosure. These files, thus, would constitute investigatory records compiled for law enforcement purposes, one of the exemptions to disclosure under the Freedom of Information Act. In the case of patient safety work product that is not otherwise subject to a statutory exception permitting disclosure, the Patient Safety Act prohibits the disclosure of such information in response to a Freedom of Information Act request. See section 922(a)(3) of the Public Health Service Act, 42 U.S.C. 299b–22(a)(3).

The Secretary continues to be subject to the existing HIPAA Enforcement Rule with respect to the use and disclosure of protected health information received by the Secretary in connection with a HIPAA Privacy Rule investigation or compliance review (see 45 CFR 160.310(c)(3)); these proposed provisions do not modify those regulations.

6. Proposed § 3.314—Investigational Subpoenas and Inquiries

Proposed § 3.314 provides procedures for the issuance of subpoenas to require the attendance and testimony of witnesses and the production of any other evidence, including patient safety work product, during an investigation or compliance review. We propose to issue subpoenas in the same manner as 45 CFR 160.314(a)(1)–(5) of the HIPAA Enforcement Rule, except that the term ''this part'' shall refer to 42 CFR Part 3. The language modification is necessary to reference the appropriate authority.

We also propose that the Secretary is permitted to conduct investigational inquiries in the same manner as the provisions of 45 CFR 160.314(b)(1)–(9) of the HIPAA Enforcement Rule. The referenced provisions describe the manner in which investigational inquiries will be conducted.

7. Proposed § 3.402—Basis for a Civil Money Penalty

Under proposed § 3.402, a person who discloses identifiable patient safety work product in knowing or reckless violation of the confidentiality provisions shall be subject to a civil money penalty of not more than $10,000 for each act constituting a violation. See section 922(f)(1) of the Public Health Service Act, 42 U.S.C. 299b–22(f)(1).

(A) Proposed § 3.402(a)—General Rule

Proposed § 3.402(a) would allow the Secretary to impose a civil money penalty on any person which the Secretary determines has knowingly or recklessly violated the confidentiality provisions. This provision is based on the language in section 922(f) of the Public Health Service Act, 42 U.S.C. 299b–22(f), that ''a person who discloses identifiable patient safety work product in knowing or reckless violation of subsection (b) shall be subject to a civil money penalty of not more than $10,000 for each act constituting such violation.''

A civil money penalty may only be imposed if the Secretary first establishes a wrongful disclosure (i.e., (1) the information disclosed was identifiable patient safety work product; (2) the information was disclosed; and (3) the manner of the disclosure does not fit within any permitted exception). If a wrongful disclosure is established, the Secretary must then determine whether the person making the disclosure acted ''knowingly'' or ''recklessly.''

The applicable law on the issue of ''knowing'' provides that ''unless the

text of the statute dictates a different result, the term 'knowingly' merely requires *proof of knowledge of the facts that constitute the offense* [rather than] a culpable state of mind or [] knowledge of the law.'' *Bryan* v. *United States,* 524 U.S. 184 (1998) (emphasis added). Applying this meaning in the context of the Patient Safety Act, the Secretary would not need to prove that the person making the disclosure knew the law (i.e., knew that the disclosed information constituted identifiable patient safety work product or that such disclosure did not meet one of the standards for a permissive disclosure in the Patient Safety Act). Rather, the Secretary would only need to show that the person knew a disclosure was being made. Although knowledge that disclosed information is patient safety work product is not required, circumstances in which a person can show no such knowledge and no reason to know such knowledge may warrant discretion by the Secretary. By contrast, as a person's opportunity for knowledge and disregard of that opportunity increases, the Secretary's compulsion to exercise discretion not to impose a penalty declines.

Where a ''knowing'' violation cannot be established, the Secretary can still impose a civil money penalty by showing that the person was reckless in making the disclosure of identifiable patient safety work product. A person acts recklessly if they are aware, or a reasonable person in their situation should be aware, that their conduct creates a substantial risk of disclosure of information and to disregard such risk constitutes a gross deviation from reasonable conduct. A ''substantial risk'' represents a significant threshold, more than the mere possibility of disclosure of patient safety work product. Whether a risk is ''substantial'' is a fact-specific inquiry. Additionally, whether a reasonable person in the situation should know of a risk is based on context. For example, an employee whose job duties regularly involve working with sensitive patient information may be expected to know of disclosure risks of which other types of employees may reasonably be unaware.

Finally, the disregarding of the risk must be a gross deviation from reasonable conduct. This gross deviation standard is commonly used to describe reckless conduct. See, e.g., Model Penal Code § 2A1.4(2006), definition of ''reckless'' for purposes of involuntary manslaughter; Black's Law Dictionary (8th ed., 2004). This does not mean that the conduct itself must be a gross deviation from reasonable conduct. Rather, the standard is whether the disregarding of the risk was a gross deviation (i.e., whether a reasonable person who is aware of the substantial risk of making an impermissible disclosure would find going forward despite the risk to be grossly unreasonable). Thus, disclosures that violate this Part and occur because an individual acted despite knowing of, or having reason to know of, a grossly unreasonable risk of disclosure are punishable by civil money penalty, regardless of whether such conduct may otherwise be widespread in the industry.

An example of a reckless disclosure of identifiable patient safety work product would be leaving a laptop unattended in a public area and accessible to unauthorized persons with identifiable patient safety work product displayed on the laptop screen. Such a situation would be reckless because it would create a substantial risk of disclosure of the information displayed on the laptop screen. If a person did not remove the identifiable patient safety work product from the laptop screen or take other measures to prevent the public view of the laptop screen, then leaving the laptop unattended would be a disregard for the substantial risk of disclosure that would be a gross deviation from reasonable conduct. Under these circumstances, the person leaving the laptop unattended could be liable for a civil money penalty.

The use of the term ''shall be subject to'' in section 922(f) of the Public Health Service Act, 42 U.S.C. 299b–22(f), conveys authority to the Secretary to exercise discretion as to whether to impose a penalty for a knowing or reckless violation of the confidentiality provisions. Based on the nature and circumstances of a violation and whether such violation was done in a knowing or reckless manner, the Secretary may impose a civil money penalty, require a corrective action plan, or seek voluntary compliance with these regulations.

Even in cases that constitute violations of the confidentiality provisions, the Secretary may exercise discretion. For example, in a situation where a provider makes a good faith attempt to assert the patient safety work product privilege, but is nevertheless ordered by a court to make a disclosure, and the provider does so, the Secretary could elect not to impose a civil money penalty. Thus, for example, it is not the Secretary's intention to impose a civil money penalty on a provider ordered by a court to produce patient safety work product where the provider has deliberately and in good faith undertaken reasonable steps to avoid such production and is, nevertheless, faced with compelled production or being held in contempt of court.

Similarly, an individual may innocently come into possession of information, unaware of the fact that the information is patient safety work product, and may innocently share the information in a manner not permitted by the confidentiality provisions. In such circumstances, the Secretary would look at the facts and circumstances of the case and could elect not to impose a penalty. Relevant facts and circumstances might include the individual's relationship with the source of the information (e.g., whether the information originated with a health care provider or a patient safety organization for which the individual was employed); whether, and the extent to which, the individual had a basis to know the information was patient safety work product or to know that the information was confidential; to whom the information was disclosed; and the intent of the individual in making the disclosure.

(B) Proposed § 3.402(b)—Violations Attributed to a Principal

The proposed rule includes a provision, at proposed § 3.402(b), that addresses the liability of a principal for a violation by a principal's agent. Proposed § 3.402(b) adopts the principle that the federal common law of agency applies when addressing the liability of a principal for the acts of his or her agent. Under this principle, a provider, PSO or responsible person generally can be held liable for a violation based on the actions of any agent, including an employee or other workforce member, acting within the scope of the agency or employment. This liability is separate from the underlying liability attributable to the agent and could result in a separate and exclusive civil money penalty. In other words, a principal may be liable for a $10,000 civil money penalty and an agent may be liable for a separate $10,000 civil money penalty arising from the same act that is a violation.

Section 922(f)(2) of the Public Health Service Act, 42 U.S.C. 299b–22(f)(2), provides that ''the provisions of section 1128A * * * shall apply to civil money penalties under this subsection [of the Patient Safety Act] in the same manner as such provisions apply to a penalty or proceeding under section 1128A.'' Section 1128A(*l*) of the Social Security Act, 42 U.S.C. 1320a–7a(*l*), establishes that ''a principal is liable for penalties * * * under this section for the actions of the principal's agents acting within the scope of the agency.'' This is similar

to the traditional rule of agency in which principals are vicariously liable for the acts of their agents acting within the scope of their authority. See *Meyer* v. *Holley,* 537 U.S. 280 (2003). Therefore, a provider, PSO or responsible person generally will be responsible for the actions of its workforce members within the scope of agency, such as where an employee discloses confidential patient safety work product in violation of the confidentiality provisions during the course of his or her employment.

The determination of whether or not a principal is responsible for a violation would be based on two fact-dependent determinations. First, the Secretary must find that a principal-agent relationship exists between the person doing the violative act and the principal. If a principal-agent relationship is established, then a second determination, whether the act in violation of the confidentiality provisions was within the scope of the agency, must be made. The determination as to whether an agent's conduct is outside the scope of the agency will be dependent upon the application of the federal common law of agency to the facts.

The purpose of applying the federal common law of agency to determine when a provider, PSO, or responsible person is vicariously liable for the acts of its agents is to achieve nationwide uniformity in the implementation of the confidentiality provisions and nationwide consistency in the enforcement of these rules by OCR. Reliance on State law could introduce inconsistency in the implementation of the patient safety work product confidentiality provisions by persons or entities in different States.

Federal Common Law of Agency

A principal's liability for the actions of its agents is generally governed by State law. However, the U.S. Supreme Court has provided that the federal common law of agency may be applied where there is a strong governmental interest in nationwide uniformity and a predictable standard, and when the federal rule in question is interpreting a federal statute. *Burlington Indus.* v. *Ellerth,* 524 U.S. 742 (1998).

The confidentiality and enforcement provisions of this regulation interpret a federal statute, the Patient Safety Act. Under the Patient Safety Act, there is a strong interest in nationwide uniformity in the confidentiality provisions and how those provisions are enforced. The fundamental goal of the Patient Safety Act is to promote the examination and correction of patient safety events in order to improve patient safety and create a culture of patient safety in the health care system. Therefore, it is essential for the Secretary to apply one consistent body of law regardless of where an agent is employed, an alleged violation occurred, or an action is brought. The same considerations support a strong federal interest in the predictable operation of the confidentiality provisions, to ensure that persons using patient safety work product can do so consistently so as to facilitate the appropriate exchange of information. Thus, the tests for application of the federal common law of agency are met.

Where the federal common law of agency applies, the courts often look to the Restatement (Second) of Agency (1958) (Restatement) as a basis for explaining the common law's application. While the determination of whether an agent is acting within the scope of its authority must be decided on a case-by-case basis, the Restatement provides guidelines for this determination. Section 229 of the Restatement provides:

(1) To be within the scope of the employment, conduct must be of the same general nature as that authorized, or incidental to the conduct authorized.

(2) In determining whether or not the conduct, although not authorized, is nevertheless so similar to or incidental to the conduct authorized as to be within the scope of employment, the following matters of fact are to be considered;

(a) Whether or not the act is one commonly done by such servants;

(b) The time, place and purpose of the act;

(c) The previous relations between the master and the servant;

(d) The extent to which the business of the master is apportioned between different servants;

(e) Whether or not the act is outside the enterprise of the master or, if within the enterprise, has not been entrusted to any servant;

(f) Whether or not the master has reason to expect that such an act will be done;

(g) The similarity in quality of the act done to the act authorized;

(h) Whether or not the instrumentality by which the harm is done has been furnished by the master to the servant;

(i) The extent of departure from the normal method of accomplishing an authorized result; and

(j) Whether or not the act is seriously criminal.

In some cases, under federal agency law, a principal may be liable for an agent's acts even if the agent acts outside the scope of its authority. Restatement (Second) of Agency section 219 (1958). However, proposed § 3.402(b) would follow section 1128A(l) of the Social Security Act, 42 U.S.C. 1320a–7a(l), which limits liability for the actions of an agent to those actions that are within the scope of the agency.

Agents

Various categories of persons may be agents of a provider, PSO, or responsible person. These persons include workforce members. We propose a slightly expanded definition of ''workforce'' from the term defined in the HIPAA Privacy Rule. The proposed definition of ''workforce'' includes employees, volunteers, trainees, contractors, and other persons whose conduct, in the performance of work for a provider, PSO or responsible person, is under the direct control of such principal, whether or not they are paid by the principal. Because of the ''direct control'' language of the proposed rule, we believe that all workforce members, including those who are not employees, are agents of a principal. Under the proposed rule, a principal could be liable for a violation based on an act that is a violation by any workforce member acting within the scope of employment or agency. The determinative issue is whether a person is sufficiently under the control of a person or entity and acting within the scope of the agency. Proposed § 3.402(b) creates a presumption that a workforce member is an agent of an employer.

8. Proposed § 3.404—Amount of Civil Money Penalty

Proposed § 3.404, the amount of the civil money penalty, is determined in accordance with section 922(f) of the Public Health Service Act, 42 U.S.C. 299b–22(f), and the provisions of this Part. Section 922(f)(1) of the Public Health Service Act, 42 U.S.C. 299b–22(f)(1), establishes a maximum penalty amount for violations of ''not more than $10,000'' per person for each violation. The statutory cap is reflected in proposed § 3.404(b).

The statute establishes only maximum penalty amounts, so the Secretary has the discretion to impose penalties that are less than the statutory maximum. This proposed regulation would not establish minimum penalties. Under proposed § 3.404(a), the penalty amount would be determined using the factors set forth in proposed § 3.408, subject to the statutory maximum reflected in proposed § 3.404(b).

As stated in the discussion under proposed § 3.402(b), a principal can be

held liable for the acts of its agent acting within the scope of the agency. Read together, with proposed § 3.404(b), if a principal and an agent are determined to be liable for a single act that is a violation, the Secretary may impose a penalty of up to $10,000 against each separately. That is, the $10,000 limit applies to each person separately, not the act that was a violation. Thus, in the circumstance where an agent and a principal are determined to have violated the confidentiality provisions, the Secretary may impose a civil money penalty of up to $10,000 against the agent and a civil money penalty of up to $10,000 against the principal, for a total of $20,000 for a single act that is a violation.

9. Proposed § 3.408—Factors Considered in Determining the Amount of a Civil Money Penalty

Section 1128A(d) of the Social Security Act, 42 U.S.C. 1320a-7a(d), made applicable to the imposition of civil money penalties by section 922(f)(2) of the Public Health Service Act, 42 U.S.C. 299b–22(f)(2), requires that, in determining the amount of ''any penalty,'' the Secretary shall take into account: (1) The nature of the claims and the circumstances under which they were presented, (2) the degree of culpability, history of prior offenses, and financial condition of the person presenting the claims, and (3) such other matters as justice may require. This language establishes factors to be considered in determining the amount of a civil money penalty.

This approach is taken in other regulations that cross-reference section 1128A of the Social Security Act, 42 U.S.C. 1320a–7a, which rely on these factors for purposes of determining civil money penalty amounts. See, for example, 45 CFR 160.408. The factors listed in section 1128A(d) of the Social Security Act, 42 U.S.C. 1320a–7a(d), were drafted to apply to violations involving claims for payment under federally funded health programs. Because Patient Safety Act violations will not be about specific claims, we propose to tailor the section 1128A(d) factors to violations of the confidentiality provisions and further particularize the statutory factors by providing discrete criteria, as done in the HIPAA Enforcement Rule and the OIG regulations that implement section 1128A of the Social Security Act, 42 U.S.C. 1320a–7a. Consistent with these other regulations, and to provide more guidance to providers, PSOs, and responsible persons as to the factors that would be used in calculating civil money penalties, we propose the following detailed factors:

(1) The nature of the violation.

(2) The circumstances and consequences of the violation, including the time period during which the violation occurred; and whether the violation caused physical or financial harm or reputational damage.

(3) The degree of culpability of the respondent, including whether the violation was intentional, and whether the violation was beyond the direct control of the respondent.

(4) Any history of prior compliance with the confidentiality provisions, including violations, by the respondent, and whether the current violation is the same as or similar to prior violation(s), whether and to what extent the respondent has attempted to correct previous violations, how the respondent has responded to technical assistance from the Secretary provided in the context of a compliance effort, and how the respondent has responded to prior complaints.

(5) The financial condition of the respondent, including whether the respondent had financial difficulties that affected its ability to comply, whether the imposition of a civil money penalty would jeopardize the ability of the respondent to continue to provide health care or patient safety activities, and the size of the respondent.

(6) Such other matters as justice may require.

For further discussion of these factors, please see the preambles to the Interim Final Rule and the Final Rule for the HIPAA Enforcement Rule at 70 FR 20235–36, Apr. 18, 2005, and 71 FR 8407–09, Feb. 16, 2006. Meeting certain conditions, such as financial condition, is a fact-specific determination based upon the individual circumstances of the situation presented.

We seek comments regarding whether the above list of factors should be expanded to expressly include a factor for persons who self-report disclosures that may potentially violate the confidentiality provisions such that voluntary self-reporting would be a mitigating consideration when assessing a civil money penalty. Voluntary self-reporting may encourage persons to report breaches of confidentiality, particularly breaches that may otherwise go unnoticed, and to demonstrate the security practices that led to the discovery of the breach and how the breach has been remedied. However, including self-reporting as a factor may be viewed incorrectly as an additional reporting obligation to report every potentially impermissible disclosure, thereby, unnecessarily increasing administrative burdens on the Department and the individuals or entities making the self-reporting, or it may interfere with obligations to identified persons, particularly when a negotiated, contractual relationship between a provider and a PSO exists that addresses how the parties are to deal with breaches.

Respondents are responsible for raising any issues that pertain to any of the factors to the Secretary within 30 days after receiving notice from the Secretary that informal resolution attempts have not resolved the issue in accordance with proposed § 3.312(a)(3)(i). The Secretary is under no obligation to affirmatively raise any mitigating factor if a respondent fails to identify the issue. See proposed § 3.504(p).

In many regulations that implement section 1128A of the Social Security Act, 42 U.S.C. 1320a–7a, the statutory factors and/or the discrete criteria are designated as either aggravating or mitigating. For example, at 42 CFR 1003.106(b)(3) of the OIG regulations, ''history of prior offenses'' is listed as an aggravating factor and is applicable as a factor to a narrow range of prohibited conduct. However, because proposed § 3.408 will apply to a variety of persons and circumstances, we propose that factors may be aggravating or mitigating, depending on the context. For example, the factor ''time period during which the violation(s) occurred'' could be an aggravating factor if the respondent's violation went undetected for a long period of time or undetected actions resulted in multiple violations, but could be a mitigating factor if a violation was detected and corrected quickly. This approach is consistent with other regulations implementing section 1128A of the Social Security Act, 42 U.S.C. 1320a–7a. See, for example, 45 CFR 160.408.

We propose to leave to the Secretary's discretion the decision regarding when aggravating and mitigating factors will be taken into account in determining the amount of a civil money penalty. The facts of each violation will drive the determination of whether a particular factor is aggravating or mitigating.

10. Proposed § 3.414—Limitations

Proposed § 3.414 sets forth the 6-year limitations period on initiating an action for imposition of a civil money penalty provided for by section 1128A(c)(1) of the Social Security Act, 42 U.S.C. 1320a–7a(c)(1). We propose the date of the occurrence of the violation be the date from which the limitation period begins.

11. Proposed § 3.416—Authority to Settle

Proposed § 3.416 states the authority of the Secretary to settle any issue or case or to compromise any penalty during the process addressed in this Part, including cases that are in hearing. The first sentence of section 1128A(f) of the Social Security Act, 42 U.S.C. 1320a–7a(f), made applicable by section 922(f)(2) of the Public Health Service Act, 42 U.S.C. 299b–22(f)(2), states, in part, ''civil money penalties * * * imposed under this section may be compromised by the Secretary.'' This authority to settle is the same as that set forth in 45 CFR 160.416 of the HIPAA Enforcement Rule.

12. Proposed § 3.418—Exclusivity of Penalty

Proposed § 3.418 makes clear that, except as noted below, penalties imposed under this Part are not intended to be exclusive where a violation under this Part may also be a violation of, and subject the respondent to, penalties under another federal or State law. This provision is modeled on 42 CFR 1003.108 of the OIG regulations.

Proposed § 3.418(b) repeats the statutory prohibition against imposing a penalty under both the Patient Safety Act and under HIPAA for a single act or omission that constitutes a violation of both the Patient Safety Act and HIPAA. Congress recognized that there could be overlap between the confidentiality provisions and the HIPAA Privacy Rule. Because identifiable patient safety work product includes individually identifiable health information as defined under the HIPAA Privacy Rule, HIPAA covered entities could be liable for violations of the HIPAA Privacy Rule based upon a single disclosure of identifiable patient safety work product. We tentatively interpret the Patient Safety Act as only prohibiting the imposition of a civil money penalty under the Patient Safety Act when there have been civil, as opposed to criminal, penalties imposed on the respondent under the HIPAA Privacy Rule for the same single act or omission. In other words, a person could have a civil money penalty imposed against him under the Patient Safety Act as well as a criminal penalty under HIPAA for the same act or omission. However, an act that amounts to a civil violation of both the confidentiality provisions and the HIPAA Privacy Rule would be enforceable under either authority, but not both.

The decision regarding which statute applies to a particular situation will be made based upon the facts of individual situations. HIPAA covered entities that seek to disclose confidential patient safety work product that contains protected health information must know when such disclosure is permissible under both statutes.

13. Proposed § 3.420—Notice of Proposed Determination

Proposed § 3.420 sets forth the requirements for the notice to a respondent sent when the Secretary proposes a penalty under this Part. This notice implements the requirement for notice contained in section 1128A(c)(1) of the Social Security Act, 42 U.S.C. 1320a–7a(c)(1). These requirements are substantially the same as those in the HIPAA Enforcement Rule at 45 CFR 160.420, except for the removal of provisions related to statistical sampling.

The notice provided for in this section must be given whenever a civil money penalty is proposed. The proposed requirements of this section serve to inform any person under investigation of the basis for the Secretary's proposed civil money penalty determination. These requirements include the statutory basis for a penalty, a description of the findings of fact regarding the violation, the reasons the violation causes liability, the amount of the proposed penalty, factors considered under proposed § 3.408 in determining the amount of the penalty, and instructions for responding to the notice, including the right to a hearing.

At this point in the process, the Secretary may also send a notice of proposed determination to a principal based upon liability for a violation under proposed § 3.402(b).

14. Proposed § 3.422—Failure To Request a Hearing

Under proposed § 3.422, when a respondent does not timely request a hearing on a proposed civil money penalty, the Secretary may impose the civil money penalty or any less severe civil money penalty permitted by section 1128A(d)(5) of the Social Security Act, 42 U.S.C. 1320a–7a(d)(5). Once the time has expired for the respondent to file for an appeal, the Secretary will decide whether to impose the civil money penalty and provide notice to the respondent of the civil money penalty. If the Secretary does pursue a civil money penalty, the civil money penalty is final, and the respondent has no right to appeal a civil money penalty imposed under these circumstances. This section is similar to 45 CFR 160.422 of the HIPAA Enforcement Rule.

For purposes of determining when subsequent actions may commence, such as collection of an imposed civil money penalty, we propose that the penalty be final upon receipt of a penalty notice sent by certified mail return receipt requested.

15. Proposed § 3.424—Collection of Penalty

Proposed § 3.424 provides that once a determination to impose a civil money penalty has become final, the civil money penalty must be collected by the Secretary, unless compromised, and prescribes the methods for collection. We propose that civil money penalties be collected as set forth under the HIPAA Enforcement Rule at 45 CFR 160.424, except that the term ''this part'' shall refer to 42 CFR Part 3. The modification is made for the provision to refer to the appropriate authority.

16. Proposed § 3.426—Notification of the Public and Other Agencies

Proposed § 3.426 would implement section 1128A(h) of the Social Security Act, 42 U.S.C. 1320a–7a(h). When a civil money penalty proposed by the Secretary becomes final, section 1128A(h) of the Social Security Act, 42 U.S.C. 1320a–7a(h), directs the Secretary to notify appropriate State or local agencies, organizations, and associations and to provide the reasons for the civil money penalty. We propose to add the public generally as a group that may receive notice, in order to make the information available to anyone who must make decisions with respect to persons that have had a civil money penalty imposed for violation of the confidentiality provisions. For instance, knowledge of the imposition of a civil money penalty for violation of the Patient Safety Act could be important to hospitals, other health care organizations, health care consumers, as well as to current and future business partners throughout the industry.

The basis for this public notice portion lies in the Freedom of Information Act, 5 U.S.C. 552. The Freedom of Information Act requires final opinions and orders made in adjudication cases to be made available for public inspection and copying. See 5 U.S.C. 552(a)(2)(A). While it is true that section 1128A(h) of the Social Security Act, 42 U.S.C. 1320a–7a(h), does not require that such notice be given to the public, neither does it prohibit such wider dissemination of that information, and nothing in section 1128A(h) of the Social Security Act, 42 U.S.C. 1320a–7a(h), suggests that it modifies the Secretary's obligations under the Freedom of Information Act.

The Freedom of Information Act requires making final orders or opinions available for public inspection and copying by ''computer telecommunication * * * or other electronic means,'' which would encompass a display on the Department's Web site. See 5 U.S.C. 552(a)(2).

A civil money penalty is considered to be final, for purposes of notification, when it is a final agency action (i.e., the time for administrative appeal has run or the adverse administrative finding has otherwise become final). The final opinion or order that is subject to the notification provisions of this section is the notice of proposed determination, if a request for hearing is not timely filed, the decision of the ALJ, if that is not appealed, or the final decision of the Board.

Currently final decisions of the ALJs and the Board are made public via the Board's Web site. *See http://www.hhs.gov/dab/search.html.* Such postings, however, would not include penalties that become final because a request for hearing was not filed under proposed § 3.504(a). Under proposed § 3.426, notices of proposed determination under proposed § 3.420 that become final because a hearing has not been timely requested, would also be made available for public inspection and copying as final orders, with appropriate redaction of any patient safety work product or other confidential information, via OCR's Web site. See the OCR patient safety Web site at *http://www.hhs.gov/ocr/PSQIA.* By making the entire final opinion or order available to the public, the facts underlying the penalty determination and the law applied to those facts will be apparent. Given that information, the public may discern the nature and extent of the violation as well as the basis for imposition of the civil money penalty.

The regulatory language would provide for notification in such manner as the Secretary deems appropriate. Posting to a Department Web site and/or the periodic publication of a notice in the **Federal Register** are among the methods which the Secretary is considering using for the efficient dissemination of such information. These methods would avoid the need for the Secretary to determine which entities, among a potentially large universe, should be notified and would also permit the general public served by providers, PSOs, and responsible persons upon whom civil money penalties have been imposed—as well as their business partners—to be apprised of this fact, where that information is of interest to them. While the Secretary could provide notice to individual agencies where desired, the Secretary could, at his option, use a single public method of notice, such as posting to a Department Web site, to satisfy the obligation to notify the specified agencies and the public.

17. Proposed § 3.504—Procedures for Hearings

Proposed § 3.504 is a compilation of procedures related to administrative hearings on civil money penalties imposed by the Secretary. The proposed section sets forth the authority of the ALJ, the rights and burdens of proof of the parties, requirements for the exchange of information and pre-hearing, hearing, and post-hearing processes. These individual sections are described in greater detail below.

This proposed section cross-references the HIPAA Enforcement Rule extensively due to the similar nature of the enforcement and appeal procedures, the nature of the issues and substance presented, and the parties most affected by these proposed regulations. We intend that the provisions of the HIPAA Enforcement Rule will be applied to the imposition of civil money penalties under this Subpart in the same manner as they are applied to violations of the HIPAA administrative simplification provisions, subject to any modifications set forth in proposed § 3.504. We believe the best and most efficient manner of achieving this result is through explicitly referencing and adopting the relevant provisions of the HIPAA Enforcement Rule. Where modifications are necessary to address the differences between the appeals of determinations under the HIPAA Enforcement Rule and the Patient Safety Act, we have made specific exceptions that we discuss below.

We note that the recently published Notice of Proposed Rulemaking entitled ''Revisions to Procedures for the Departmental Appeals Board and Other Departmental Hearings'' (see 72 FR 73708 (December 28, 2007)) proposes to modify the HIPAA Enforcement Rule, which we reference extensively in this proposed rule. Our intent for the patient safety regulations would be to maintain the alignment between the patient safety enforcement process and the HIPAA Enforcement Rule, as stated previously. Should the amendments to the HIPAA Enforcement Rule become final based on that Notice of Proposed Rulemaking, our intent would be to incorporate those changes in any final rulemaking here. That Notice of Proposed Rulemaking proposes to amend 45 CFR 160.508(c) and 45 CFR 160.548, and to add a new provision, 45 CFR 160.554, providing that the Secretary may review all ALJ decisions that the Board has declined to review and all Board decisions for error in applying statutes, regulations or interpretive policy.

18. Proposed § 3.504(a)—Hearings Before an ALJ

Proposed § 3.504(a) provides the time and manner in which a hearing must be requested, or dismissed when not timely requested. This proposed section applies the same regulations as the HIPAA Enforcement Rule cited at 45 CFR 160.504(a)–(d), except that the language in paragraph (c) of 45 CFR 160.504 following and including ''except that'' does not apply. The excluded provision refers to the ability of respondents to raise an affirmative defense under 45 CFR 160.410(b)(1) for which we have not adopted a comparable provision because the provision implements a statutory defense unique to HIPAA.

19. Proposed § 3.504(b)—Rights of the Parties

Proposed § 3.504(b) provides that the rights of the parties not specifically provided elsewhere in this Part shall be the same as those provided in 45 CFR 160.506 of the HIPAA Enforcement Rule.

20. Proposed § 3.504(c)—Authority of the ALJ

Proposed § 3.504(c) provides that the general guidelines and authority of the ALJ shall be the same as provided in the HIPAA Enforcement Rule at 45 CFR 160.508(a)–(c)(4). We exclude the provision at 45 CFR 160.508(c)(5) because there is no requirement under the Patient Safety Act for remedied violations based on reasonable cause to be insulated from liability for a civil money penalty.

21. Proposed § 3.504(d)—Ex parte Contacts

Proposed § 3.504(d) is designed to ensure the fairness of the hearing by prohibiting ex-parte contacts with the ALJ on matters at issue. We propose to incorporate the same restrictions as provided for in the HIPAA Enforcement Rule at 45 CFR 160.510.

22. Proposed § 3.504(e)—Prehearing Conferences

Proposed § 3.504(e) adopts the same provisions as govern prehearing conferences in the HIPAA Enforcement Rule at 45 CFR 160.512, except that the term ''identifiable patient safety work product'' is substituted for ''individually identifiable health

information.'' Under this proposed provision, the ALJ is required to schedule at least one prehearing conference, in order to narrow the issues to be addressed at the hearing and, thus, expedite the formal hearing process, and to prescribe a timeframe for prehearings.

23. Proposed § 3.504(f)—Authority To Settle

Proposed § 3.504(f) adopts 45 CFR 160.514 of the HIPAA Enforcement Rule. This proposal provides that the Secretary has exclusive authority to settle any issue or case at any time and need not obtain the consent of the ALJ.

24. Proposed § 3.504(g)—Discovery

We propose in § 3.504(g) to adopt the discovery procedures as provided for in the HIPAA Enforcement Rule at 45 CFR 160.516. These provisions allow limited discovery in the form of the production for inspection and copying of documents that are relevant and material to the issues before the ALJ. These provisions do not authorize other forms of discovery, such as depositions and interrogatories.

Although the adoption of 45 CFR 160.516 would permit parties to raise claims of privilege and permit an ALJ to deny a motion to compel privileged information, a respondent could not claim privilege, and an ALJ could not deny a motion to compel, if the Secretary seeks patient safety work product relevant to the alleged confidentiality violation because the patient safety work product would not be privileged under proposed § 3.204(c).

Under this proposal, a respondent concerned with potential public access to patient safety work product may raise the issue before the ALJ and seek a protective order. The ALJ may, for good cause shown, order appropriate redactions made to the record after hearing. See proposed § 3.504(s).

25. Proposed § 3.504(h)—Exchange of Witness Lists, Witness Statements, and Exhibits

Proposed § 3.504(h) provides for the prehearing exchange of certain documents, including witness lists, copies of prior statements of witnesses, and copies of hearing exhibits. We propose that the requirements set forth in 45 CFR 160.518 of the HIPAA Enforcement Rule shall apply, except that the language in paragraph (a) of 45 CFR 160.518 following and including ''except that'' shall not apply. We exclude the provisions relating to the provision of a statistical expert's report not less than 30 days before a scheduled hearing because we do not propose language permitting the use of statistical sampling to estimate the number of violations.

26. Proposed § 3.504(i)—Subpoenas for Attendance at Hearing

Proposed § 3.504(i) provides procedures for the ALJ to issue subpoenas for witnesses to appear at a hearing and for parties and prospective witnesses to contest such subpoenas. We propose to adopt the same regulations as provided at 45 CFR 160.520 of the HIPAA Enforcement Rule.

27. Proposed § 3.504(j)—Fees

Proposed § 3.504(j) provides for the payment of witness fees by the party requesting a subpoena. We propose that the fees requirements be the same as those provided in 45 CFR 160.522 of the HIPAA Enforcement Rule.

28. Proposed § 3.504(k)—Form, Filing and Service of Papers

Proposed § 3.504(k) provides requirements for documents filed with the ALJ. We propose to adopt the requirements of 45 CFR 160.524 of the HIPAA Enforcement Rule.

29. Proposed § 3.504(l)—Computation of Time

Proposed § 3.504(l) provides the method for computing time periods under this Part. We propose to adopt the requirements of 45 CFR 160.526 of the HIPAA Enforcement Rule, except the term ''this subpart'' shall refer to 42 CFR Part 3, Subpart D and the citation ''§ 3.504(a) of 42 CFR Part 3'' shall be substituted for the citation ''§ 160.504.''

30. Proposed § 3.504(m)—Motions

Proposed § 3.504(m) provides requirements for the content of motions and the time allowed for responses. We propose to adopt the requirements of 45 CFR 160.528 of the HIPAA Enforcement Rule.

31. Proposed § 3.504(n)—Sanctions

Proposed § 3.504(n) provides the sanctions an ALJ may impose on parties and their representatives for failing to comply with an order or procedure, failing to defend an action, or other misconduct. We propose to adopt the provisions of 45 CFR 160.530 of the HIPAA Enforcement Rule.

32. Proposed § 3.504(o)—Collateral Estoppel

Proposed § 3.504(o) would adopt the doctrine of collateral estoppel with respect to a final decision of an administrative agency. Collateral estoppel means that determinations made with respect to issues litigated and determined in a proceeding between two parties will bind the respective parties in later disputes concerning the same issues and parties. We propose to adopt the provisions of 45 CFR 160.532 of the HIPAA Enforcement Rule, except that the term ''a confidentiality provision'' shall be substituted for the term ''an administrative simplification provision''.

33. Proposed § 3.504(p)—The Hearing

Proposed § 3.504(p) provides for a public hearing on the record, the burden of proof at the hearing and the admission of rebuttal evidence. We propose to adopt the provisions of 45 CFR 160.534 of the HIPAA Enforcement Rule, except the following text shall be substituted for § 160.534(b)(1): ''The respondent has the burden of going forward and the burden of persuasion with respect to any challenge to the amount of a proposed penalty pursuant to §§ 3.404–3.408 of 42 CFR Part 3, including any factors raised as mitigating factors.'' We propose to adopt this new language for § 160.534(b)(1) because references to affirmative defenses in the excluded text are not applicable in the context of the Patient Safety Act as such defenses are under the HIPAA Enforcement Rule; nor does the Patient Safety Act include provisions for the waiver or reduction of a civil money penalty in accordance with 45 CFR 160.412.

45 CFR 160.534(c) states that the hearing must be open to the public unless otherwise ordered by the ALJ for good cause shown. In proposed § 3.504(p) of this Subpart, we propose that good cause shown under 45 CFR 160.534(c) may be that identifiable patient safety work product has been introduced into evidence or is expected to be introduced into evidence. Protecting patient safety work product is important and is an issue about which all parties and the ALJ should be concerned.

34. Proposed § 3.504(q)—Witnesses

Under proposed § 3.504(q), the ALJ may allow oral testimony to be admitted or provided in the form of a written statement or deposition so long as the opposing party has a sufficient opportunity to subpoena the person whose statement is being offered. We propose to adopt the provisions of 45 CFR 160.538 of the HIPAA Enforcement Rule, except that the citation ''§ 3.504(h) of 42 CFR Part 3'' shall be substituted for the citation ''§ 160.518.''

35. Proposed § 3.504(r)—Evidence

Proposed § 3.504(r) would provide guidelines for the acceptance of evidence in hearings. We propose to adopt the provisions of 45 CFR 160.540 of the HIPAA Enforcement Rule, except that the citation ''§ 3.420 of 42 CFR Part 3'' shall be substituted for the citation ''§ 160.420 of this part''.

In the same manner as the exception to privilege for enforcement activities under § 3.204(c) applies to proposed § 3.504(g), the exception to privilege applies under proposed § 3.504(r) as well. Although the adoption of 45 CFR 160.540(e) would permit parties to raise claims of privilege and permit an ALJ to exclude from evidence privileged information, a respondent could not claim privilege and an ALJ could not exclude identifiable patient safety work product if the Secretary seeks to introduce that patient safety work product because disclosure of the patient safety work product would not be a violation of the privilege and confidentiality provisions under proposed § 3.204(c).

36. Proposed § 3.504(s)—The Record

Proposed § 3.504(s) provides for recording and transcription of the hearing, and for the record to be available for inspection and copying by any person. We propose to adopt the provisions at 45 CFR 160.542 of the HIPAA Enforcement Rule. We also propose to provide that good cause for making appropriate redactions includes the presence of identifiable patient safety work product in the record.

37. Proposed § 3.504(t)—Post-Hearing Briefs

Proposed § 3.504(t) provides that the ALJ has the discretion to order post-hearing briefs, although the parties may file post-hearing briefs in any event if they desire. We propose to adopt the provisions of 45 CFR 160.544 of the HIPAA Enforcement Rule.

38. Proposed § 3.504(u)—ALJ's Decision

Proposed § 3.504(u) provides that not later than 60 days after the filing of post-hearing briefs, the ALJ shall serve on the parties a decision making specific findings of fact and conclusions of law. The ALJ's decision is the final decision of the Secretary, and will be final and binding on the parties 60 days from the date of service of the ALJ decision, unless it is timely appealed by either party. We propose to adopt the provisions of 45 CFR 160.546 of the HIPAA Enforcement Rule, except the citation ''§ 3.504(v) of 42 CFR Part 3'' shall be substituted for ''§ 160.548.''

39. Proposed § 3.504(v)—Appeal of the ALJ's Decision

Proposed § 3.504(v) provides for manner and time for review of an ALJ's decision regarding penalties imposed under this Part and subsequent judicial review. We propose to adopt the same provisions as 45 CFR 160.548 of the HIPAA Enforcement Rule, except the following language in paragraph (e) of 45 CFR 160.548 shall not apply: ''Except for an affirmative defense under § 160.410(b)(1) of this part.'' We exclude this language because the Patient Safety Act does not provide for affirmative defenses in the same manner as HIPAA.

40. Proposed § 3.504(w)—Stay of the Secretary's Decision

Proposed § 3.504(w) provides that a respondent may request a stay of the effective date of a penalty pending judicial review. We propose to adopt the provisions of 45 CFR 160.550 of the HIPAA Enforcement Rule to govern this process.

41. Proposed § 3.504(x)—Harmless Error

Proposed § 3.504(x) adopts the ''harmless error'' standard as expressed in the HIPAA Enforcement Rule at 45 CFR 160.522. This proposed rule provides that the ALJ and the Board at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

IV. Impact Statement and Other Required Analyses

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act requires that a covered agency prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. The Department has determined that this proposed rule would not impose a mandate that will result in the expenditure by State, Local, and Tribal governments, in the aggregate, or by the private sector, of more than $100 million in any one year.

Paperwork Reduction Act

This notice of proposed rulemaking adding a new Part 3 to volume 42 of the Code of Federal Regulations contains information collection requirements. This summary includes the estimated costs and assumptions for the paperwork requirements related to this proposed rule. A copy of the information collection request will be available on the PSO Web site (*www.pso.ahrq.gov*) and can be obtained in hardcopy by contacting Susan Grinder at the Center for Quality Improvement and Patient Safety, AHRQ, (301) 427–1111 (o); (301) 427–1341 (fax). These paperwork requirements have been submitted to the Office of Management and Budget for review under number xxxx–xxxx as required by 44 U.S.C. 3507(a)(1)(c) of the Paperwork Reduction Act of 1995, as amended (PRA). Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

With respect to proposed § 3.102 concerning the submission of certifications for initial and continued listing as a PSO, and of updated information, all such information would be submitted on Form SF–XXXX. To maintain its listing, a PSO must also submit a brief attestation, once every 24-month period after its initial date of listing, submitted on Form SF–XXXX, stating that it has entered contracts with two providers. We estimate that the proposed rule would create an average burden of 30 minutes annually for each entity that seeks to become a PSO to complete the necessary certification forms. Table 1 summarizes burden hours.

TABLE 1.—TOTAL BURDEN HOURS RELATED TO CERTIFICATION FORMS

[Summary of all burden hours, by Provision, for PSOs]

Provision	Annualized burden hours
3.112	30 minutes.

HHS is working with OMB to obtain approval of the associated burden in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) before the effective date of the final rule. Comments on this proposed information collection should be directed to Susan Grinder, by sending an e-mail to *Psosupport@ahrq.hhs.gov* or sending a fax to (301) 427–1341.

Under 5 CFR 1320.3(c), a covered collection of information includes the requirement by an agency of a disclosure of information to third parties by means of identical reporting, recordkeeping, or disclosure requirements, imposed on ten or more persons. The proposed rule reflects the previously established reporting requirements for breach of confidentiality applicable to business associates under HIPAA regulations requiring contracts top contain a provision requiring the business associate (in this case, the PSO) to notify

providers of breaches of their identifiable patient data's confidentiality or security. Accordingly, this reporting requirement referenced in the regulation previously met Paperwork Reduction Act review requirements.

The proposed rule requires in proposed § 3.108(c) that a PSO notify the Secretary if it intends to relinquish voluntarily its status as a PSO. The entity would be required to notify the Secretary that it has, or will soon, alert providers and other organizations from which it has received patient safety work product or data of its intention and provide for the appropriate disposition of the data in consultation with each source of patient safety work product or data held by the entity. In addition, the entity is asked to provide the Secretary with current contact information for further communication from the Secretary as the entity ceases operations. The reporting aspect of this requirement is essentially an attestation that is equivalent to the requirements for listing, continued listing, and meeting the minimum contracts requirement. This minimal data requirement would come within 5 CFR 1320.3(h)(1) which provides an exception from PRA requirements for affirmations, certifications, or acknowledgments as long as they entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument. In this case, the nature of the instrument would be an attestation that the PSO is working with its providers for the orderly cessation of activities. The following other collections of information that would be required by the proposed regulation under proposed § 3.108 are also exempt from PRA requirements pursuant to an exception in 5 CFR 1320.4 for information gathered as part of administrative investigations and actions regarding specific parties: information supplied in response to preliminary agency determinations of PSO deficiencies or in response to proposed revocation and delisting (*e.g.*, information providing the agency with correct facts, reporting corrective actions taken, or appealing proposed agency revocation decisions).

Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts State law, or otherwise has Federalism implications. The Patient Safety Act upon which the proposed regulation is based makes patient safety work product confidential and privileged. To the extent this would not be consistent with any state law, including court decisions, the Federal statute would preempt such state law or court order. The proposed rule (and subsequent final rule) will not have any greater preemptive effect on state or local governments than that imposed by the statute. While the Patient Safety Act does establish new Federal confidentiality and privilege protections for certain information, these protections only apply when health care providers work with PSOs and new processes, such as patient safety evaluation systems, that do not currently exist. These Federal data protections provide a mechanism for protection of sensitive information that could improve the quality, safety, and outcomes of health care by fostering a non-threatening environment in which information about adverse medical events and near misses can be discussed. It is hoped that confidential analysis of patient safety events will reduce the occurrence of adverse medical events and, thereby, reduce the costs arising from such events, including costs incurred by state and local governments attributable to such events.

AHRQ, in conjunction with OCR, held three public listening sessions prior to drafting the proposed rule. Representatives of several states participated in these sessions. In particular, states that had begun to collect and analyze patient safety event information spoke about their related experiences and plans. Following publication of the NPRM, AHRQ will consult with appropriate state officials and organizations to review the scope of the proposed rule and to specifically seek input on federalism issues and a proposal in the rule at proposed § 3.102(a)(2) that would limit the ability of public or private sector regulatory entities to seek listing as a PSO.

Regulatory Impact Analysis

Under Executive Order 12866 (58 FR 51735, October 4, 1993), Federal Agencies must determine whether a regulatory action is ''significant'' and, therefore, subject to OMB review and the requirements of the Executive Order. Executive Order 12866 defines ''significant regulatory action'' as one that is likely to result in a rule that may:

1. Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal government or communities.

2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

3. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

4. Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

AHRQ has accordingly examined the impact of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year). In the course of developing the proposed rule, AHRQ has considered the rule's costs and benefits, as mandated by Executive Order 12866. Although we cannot determine with precision the aggregate economic impact of the proposed rule, we believe that the impact may approach $100 million or more annually. HHS has determined that the proposed rule is ''significant'' also because it raises novel legal and policy issues with the establishment of a new regulatory framework, authorized by the Patient Safety Act, and imposes requirements, albeit voluntary, on entities that had not previously been subject to regulation in this area. Consequently, as required under Executive Order 12866, AHRQ conducted an analysis of the economic impact of the proposed rule.

Background

The Patient Safety Act establishes a framework for health care providers voluntarily to report information on the safety, quality, and outcomes of patient care that to PSOs listed by HHS. The main objectives of the Patient Safety Act are to: (1) Encourage health care providers to collect and examine patient safety events more freely and consistently than they do now, (2) encourage many provider arrangements or contracts with expert PSOs to receive, aggregate, and analyze data on patient

safety events so that PSOs may provide feedback and assistance to the provider to improve patient safety and (3) allow the providers to improve the quality of care delivered and reduce patient risk. The Patient Safety Act provides privilege from legal discovery for patient safety work product, as well as confidentiality protections in order to foster a culture of patient safety. The Patient Safety Act does not contain mandatory reporting requirements. It does, however, require information submissions by entities that voluntarily seek to be recognized, (i.e., listed) as PSOs by the Secretary.

The cost of an adverse patient safety event can be very high in terms of human life, and it also often carries a significant financial cost. The Institute of Medicine report, *To Err is Human: Building a Safer Health Care System*, estimates that adverse events cost the United States approximately $37.6 billion to $50 billion each year. ''Total national costs (lost income, lost household production, disability, and health care costs) of preventable adverse events (medical errors resulting in injury) are estimated to be between $17 billion and $29 billion, of which health care costs represent over one-half.'' [18]

The proposed rule was written to minimize the regulatory and economic burden on an entity that seeks certification as a PSO in order to collect, aggregate, and analyze confidential information reported by health care providers. Collecting, aggregating, and analyzing information on adverse events will allow problems to be identified, addressed, and eventually prevented. This, in turn, will help improve patient safety and the quality of care, while also reducing medical costs. The following analysis of costs and benefits—both quantitative and qualitative—includes estimates based on the best available health care data and demonstrates that the benefits of the proposed regulation justify the costs involved in its implementation.

The economic impact of an alternative to the proposed rule is not discussed in the following analysis because an alternative to the statutorily authorized voluntary framework is the existence of no new program, which would produce no economic change or have no economic impact, or—alternatively—a mandatory regulatory program for all health care providers, which is not authorized by the Patient Safety Act and which is necessarily not a realistic alternative and would likely be much more expensive. (A guiding principle of those drafting the regulation was to minimize the economic and regulatory burden on those entities seeking to be PSOs and providers choosing to work with PSOs, within the limits of the Patient Safety Act. Hence this proposed rule represents the Department's best effort at minimal impact while still meeting statutory provisions.)

AHRQ has relied on key findings from the literature to provide baseline measures for estimating the likely costs and benefits of the proposed rule. We believe that the costs of becoming a PSO (i.e., the costs of applying to be listed by the Secretary) will be relatively small, and the costs of operating a PSO will be small, in relation to the possible cost savings that will be derived from reducing the number of preventable adverse medical events each year.

The direct costs to individual providers of working with PSOs will vary considerably. For an institutional or individual provider that chooses to report readily accessible information to a PSO occasionally, costs may be negligible. The proposed rule does not require a provider to enter into a contract with a PSO, establish internal reporting or analytic systems, or meet specific security requirements for patient safety work product. A provider's costs will derive from its own choice whether to undertake and, if so, whether to conduct or contract for data collection, information development, or analytic functions. Such decisions will be based on the provider's assessment of the cost and benefits it expects to incur and achieve. As we discuss below, hospitals in particular have developed, and can be expected to take advantage of the protections afforded by the Patient Safety Act by expanding data collection, information development, and analytic functions at their institutions. We anticipate that many providers will choose to enter into contracts with PSOs voluntarily. If providers choose to report data routinely to a PSO, a contract will be a good business practice. It provides greater assurance that a provider can demonstrate, if its claims of protections are challenged, that it is operating in full compliance with the statute. It enables the provider to exert greater control over the use and sharing of its data and, in the case of a provider that is a covered entity under the HIPAA Privacy Rule, the provider will need to enter a business associate agreement with a PSO for compliance with that regulation if the reported data includes protected health information.

The following cost estimates represent an effort to develop an ''upper bound'' on the cost impact of the proposed rule by assuming that providers choosing to work with PSOs will follow best business practices, take full advantage of the Patient Safety Act's protections, and develop robust internal reporting and analytic systems, rather than meeting the minimal requirements of the proposed rule. The cost estimates below are based on existing hospital-based activities for reporting patient safety events, which are likely to be similar to most events that a PSO will analyze (namely quality and safety activities within hospitals). While the Patient Safety Act is not limited to hospitals, AHRQ has received indications from various stakeholder groups that hospital providers will be the predominant provider type initially interested in working with PSOs.

Affected Entities

To date, AHRQ has no hard information on the exact number of interested parties that may wish to become a PSO. AHRQ estimates, however, that 50 to 100 entities may request to become a listed PSO by the Secretary during the first three years after publication of the final rule. AHRQ anticipates a gradual increase in the number of entities seeking listing as a PSO and estimates that roughly 50 entities will seek PSO certification during Year 1, 25 entities during Year 2, and an additional 25 entities during Year 3, totaling 100 PSOs by the end of Year 3. After Year 3, we anticipate that the number of PSOs will remain about constant, with the number of new entrants roughly equivalent to the number of PSOs that cease to operate.

Healthcare providers, especially hospitals, currently assume some level of burden to collect, develop, and analyze patient safety event information similar to the information that will be reported to PSOs. We note that most institutional providers (especially larger ones) already do some of this data gathering. AHRQ anticipates that entities that currently operate internal patient safety event reporting systems either may be interested in: (1) Establishing a component organization to seek certification as a PSO; or (2) contracting with a PSO. Using data from the 2004 American Hospital Association, AHRQ conducted an analysis of the burden hours and likely costs associated with reporting patient safety event information to a PSO. See below.

[18] Corrigan, J. M., Donaldson, M. S., Kohn, L. T., McKay, T., Pike, K. C., for the Committee on Quality of Health Care in America. *To Err is Human: Building a Safer Health System.* Washington, DC.: National Academy Press; 2000.

Costs

The proposed rule enables providers to receive Federal protections for information on patient safety events that the providers choose to collect, analyze, and report in conformity with the requirements of the Patient Safety Act and the proposed rule. The proposed rule, consistent with the Patient Safety Act, does not require any entity to seek listing as a PSO and does not require any provider to work with a PSO. While all holders of patient safety work product must avoid impermissible disclosures of patient safety work product, we do not impose any specific requirements that holders must meet to comply with this obligation. The requirements of the proposed rule apply only to entities that choose to seek listing by the Secretary as a PSO. Similarly, the proposed rule does not impose requirements on States or private sector entities (including small businesses) that would result in additional spending, that is, the government is not imposing any direct costs on States or the private sector.

The Patient Safety Act, and therefore, the proposed rule, does impose obligations on entities that are listed by the Secretary as PSOs. Every PSO must carry out eight patient safety activities and comply with seven statutory criteria during its period of listing, including requirements related to the provision of security for patient safety work product, the ability to receive and analyze data from providers and assist them in implementing system improvements to mitigate or eliminate potential risk or harm to patients from the delivery of health care services.[19] Because this is a new, untested, and voluntary initiative—coupled with the fact that PSOs currently do not exist—AHRQ does not have data on PSO fees, income, or expenses to estimate the precise monetized and non-monetized costs and benefits of the proposed rule. The following estimates reflect the cost of all incremental activities required (or contemplated) by the proposed rule.

For entities that seek to be listed as a PSO by the Secretary, AHRQ assumes that most of the total costs incurred will be for the establishment of a new organizational structure. AHRQ expects such costs to vary considerably based on the types of entities that request PSO listing (e.g., size; geographic location; setting; academic, professional, or business affiliation; and whether or not the entity is a component of a parent organization). It is anticipated that the proposed rule's cost to a PSO will likely be highest in the first year due to start-up and initial operational costs and establishment of policies and procedures for complying with PSO regulations. PSO operational costs will include the hiring of qualified staff, setting up data collection and reporting systems, establishing policies and procedures for ensuring data security and confidentiality, maintaining a patient safety evaluation system as required by the Patient Safety Act, and receiving and generating patient safety work product. The fact that PSOs are new entities for which there are no existing financial data means that estimates of the cost or charges for PSO services are a matter of speculation at this time. Additionally, the degree to which PSOs will exercise market power, what services they will offer, and the impact of a competitive environment is not yet known. Based on discussions with stakeholder groups, we believe that there will be a number of business models that emerge for PSOs. We anticipate that many PSOs will be components of existing organizations, which will likely subsidize the operations of their component PSOs for some time. Despite these limitations, AHRQ believes it can construct reasonable estimates of the costs and benefits of the Patient Safety Act. See ''Provider—PSO Costs and Charges'' for an explanation of why the above-mentioned uncertainties do not preclude AHRQ from calculating overall costs, benefits, and net benefits of the Patient Safety Act.

As noted above, the proposed rule does not require providers to establish internal reporting or analytic systems. AHRQ expects, however, that many providers will do so in order to take full advantage of the protections of the Patient Safety Act. As a result, our estimates reflect an upper bound on the potential costs associated with implementation by assuming that all providers that choose to participate will establish robust internal reporting and analytic systems.

AHRQ recognizes that many state governments, public and private health care purchasers, and private accrediting and certifying organizations already employ voluntary and/or mandatory patient safety event reporting systems. As health care organizations increasingly focus on the monitoring of adverse events, the use of voluntary reporting systems to detect, evaluate, and track such events has also increased. Preliminary findings from AHRQ's Adverse Event Reporting Survey, conducted by the RAND Corporation (RAND) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), show that 98 percent of hospitals are already reporting adverse medical events.[20] This survey was administered to a representative sample of 2,000 hospitals, with an 81 percent response rate. Thus, it is anticipated that the associated costs of the proposed rule for hospitals with existing patient safety event reporting systems will be very minimal, because the majority of these organizations already have the institutional infrastructure and operations to carry out the data collection activities of the proposed rule. AHRQ assumes that the estimated 2 percent of hospitals that currently have no reporting system are unlikely to initiate a new reporting system based on the proposed rule, at least in the first year that PSOs are operational.

Hospital Costs

We extrapolated findings from the RAND–JCAHO survey in order to calculate the burden hours and monetized costs associated with the proposed rule, using data from the American Hospital Association's 2004 [21] annual survey of hospitals in the United States [22] to estimate the number of hospitals nationwide. This figure served as the denominator in our analysis. We acknowledge that, over time, not all providers working with PSOs will be hospitals; however, it is reasonable to use hospitals as a basis for our initial estimates, given the preliminary indications that hospitals will be the predominant, if not exclusive, providers submitting information to PSOs during the early years in which PSOs are operational.

Based on American Hospital Association data, there are 5,759 registered U.S. hospitals—including community hospitals, Federal hospitals, non-Federal psychiatric hospitals, non-Federal long-term care hospitals, and hospital units of institutions—in which there are 955,768 staffed operational beds. Based on the RAND–JCAHO finding regarding event reporting in hospitals, AHRQ calculates that 98 percent of the 5,759 hospitals (5,644 hospitals with 936,653 staffed beds)

[19] These 15 requirements from the Patient Safety Act are discussed in proposed § 3.102(b). The eight patient safety activities are defined in proposed § 3.20 and the seven criteria are specified in proposed § 3.102(b)(2).

[20] RAND and Joint Commission on Accreditation of Healthcare Organizations. *Survey on Hospital Adverse Event Reporting Systems: Briefing on Baseline Data.* August 16, 2006 Briefing.

[21] American Hospital Association. Fast Facts on U.S. Hospitals from AHA Hospital Statistics. November 14, 2005. Available at: *http://www.aha.org/aha/resource_center/fastfacts/fast_facts_US_hospitals.html.* Web Page.

[22] The 2005 survey results will likely be release in November 2006.

already have, and are supporting the costs of, a centralized patient safety event reporting system.

AHRQ assumed that an institution will report an average of one patient safety event (including no harm events and close calls) per bed per month. Based on this assumption, AHRQ estimates that all hospitals nationwide are currently completing a total of 11,239,832 patient safety event reports per year. Based on the assumption that it takes 15 minutes to complete each patient safety event report, we estimate that hospitals are already spending 2,809,958 hours per year on this activity. At a Full-Time Equivalent (FTE) rate of $80 per hour, we estimate that all hospitals nationwide are currently spending approximately $224,796,634 per year on patient safety event reporting activities.

AHRQ estimates that, once collected, it will take an additional five minutes for hospital staff to submit patient safety event information to a PSO. We, therefore, estimate that the total burden hours for all hospitals nationwide to submit patient safety event information to a PSO totals 936,653 hours annually with an associated cost of $74,932,211 based on the assumption that all hospitals nationwide reported all possible patient safety events (using the heuristic of one event per bed per month).

During the first year following publication of the final rule PSOs will be forming themselves into organizations and engaging in startup activities. We assume that there will be a gradual increase in the number of entities seeking listing as PSOs, beginning with a 10 percent participation rate. We assume as many as 25 percent of hospitals may enter into arrangements with PSOs by the end of the first year; however, the overall effective participation rate will only average 10 percent. This assumption translates to 93,665 hours of additional burden for hospitals to report patient safety event information to PSOs with an estimated cost of $7,493,221. Assuming a 40 percent participation rate of all hospitals nationwide during the second year that PSOs are operational, there would be 374,660 burden hours with an estimated cost of $29,972,884. Assuming there is 60 percent participation rate of all hospitals nationwide during the third year that PSOs are operational, there would be 561,990 burden hours nationwide with an estimated cost of $44,959,326. (See Table 1).

In summary, the direct costs—which would be voluntarily incurred if all hospitals nationwide that choose to work with PSOs during the first five years also chose to establish systematic reporting systems—are projected to range from approximately $7.5 million to nearly $63.7 million in any single year, based on 10 percent to 85 percent participation rate among hospitals. These cost estimates may be high if provider institutions, such as hospitals, do not submit all the patient safety data they collect to a PSO. If only a fraction of the data is reported to a PSO, the cost estimates and burden will be proportionately reduced.

TABLE 1.—ESTIMATED HOSPITALS COSTS TO SUBMIT INFORMATION TO PSOS: 2008–2012

Year	2008	2009	2010	2011	2012
Hospital Penetration Rate	10%	40%	60%	75%	85%.
Hospital Cost	$7.5 M	$30.0 M	$45.0 M	$56.2 M	$63.7 M.

PSO Costs

A second category of costs, in addition to incremental costs borne by hospitals, is that of the PSOs themselves. PSO cost estimates are based on estimates of organizational and consulting capabilities and statutory requirements. We followed the standard accounting format for calculating ''independent government cost estimates,'' although the categories did not seem entirely appropriate for the private sector. In order to estimate PSO costs over a five-year period, we made several assumptions about the size and operations of new PSOs. Specifically, we assumed that PSOs would be staffed modestly, relying on existing hospital activities in reporting adverse events, and that a significant proportion of PSOs are likely to be component PSOs, with support and expertise provided by a parent organization. Our assumptions are that PSOs will hire dedicated staff of from 1.5 to 4 FTEs, assuming an average salary rate of $67/hour. We estimate that a significant overhead figure of 100%, coupled with 20% for General and Administrative (G&A) expenses, will cover the appreciable costs anticipated for legal, security, travel, and miscellaneous PSO expenses.

Although we believe that the above estimates may be conservative, we also believe that PSOs will become more effective over time without increasing staff size. Finally, we estimate that the number of PSOs will increase from 50 to 100 during the first three years in which the Secretary lists PSOs and remain at 100 PSOs in subsequent years. Table 2 summarizes PSO operational costs for the first five years based on these estimates.

TABLE 2.—TOTAL PSO OPERATIONAL COSTS: 2008–2012

Year	2008	2009	2010	2011	2012
Number of PSOs	50	75	100	100	100.
PSO Cost	$61.4 M	$92.1 M	$122.8 M	$122.8 M	$122.8 M.

Table 3 presents the total estimated incremental costs related to implementation of the Patient Safety Act, based on new activities on the part of hospitals and the formation of new entities, PSOs, from 2008–2012. Estimates for total Patient Safety Act costs are $80 million in Year 1, increasing to $186.5 million in Year 5.

TABLE 3.—TOTAL PATIENT SAFETY ACT COSTS INCLUDING HOSPITAL COSTS AND PSO COSTS: 2008–2012

Year	2008	2009	2010	2011	2012
Hospital Penetration Rate	10%	40%	60%	75%	85%.
Hospital Cost	$7.5 M	$30.0 M	$45.0 M	$56.2 M	$63.7 M.
PSO Cost	$61.4 M	$92.1 M	$122.8 M	$122.8 M	$122.8 M.
Total Cost	$68.9 M	$122.1 M	$167.8 M	$179.0 M	$186.5 M.

Provider—PSO Costs and Charges

We have not figured into our calculations any estimates for the price of PSO services, amounts paid by hospitals and other health care providers to PSOs, PSO revenues, or PSO break-even analyses. We have not speculated about subsidies or business models. Regardless of what the costs and charges are between providers and PSOs, they will cancel each other out, as expenses to providers will become revenue to PSOs.

Benefits

The primary benefit of the proposed rule is to provide the foundation for new, voluntary opportunities for health care providers to improve the safety, quality, and outcomes of patient care. The non-monetized benefits to public health from the proposed rule are clear, translating to improvements in patient safety, although such benefits are intangible and difficult to quantify, not only in monetary terms but also with respect to outcome measures such as years added or years with improved quality-of-life. Although AHRQ is unable to quantify the net benefits of this proposed rule precisely, it believes firmly that the proposed rule will be effective in addressing costly medical care problems in the health system that adversely affect patients, their families, their employees, and society in general. Finally, estimating the impact of the proposed rule in terms of measurable monetized and non-monetized benefits is a challenge due to a lack of baseline data on the incidence and prevalence of patient safety events themselves. In fact, one of the intended benefits of the Patient Safety Act is to provide more objective data in this important area, which will begin to allow tracking of improvement.

AHRQ has relied on key findings from the medical professional literature to provide a qualitative description of the scope of the problem. The Institute of Medicine reports that 44,000 to 98,000 people die in hospitals each year as a result of adverse events.[23] The Harvard Medical Practice Study found a rate of 3.7 adverse events per 100 hospital admissions.[24] Similar results were found in a replication of this study in Colorado and Utah; adverse events were reported at a rate of 2.9 per 100 admissions.[25] Adverse events do not occur only in hospitals; they also occur in physician's offices, nursing homes, pharmacies, urgent care centers, ambulatory care settings, and care delivered in the home.

The importance of evaluating the incidence and cost of adverse events cannot be underestimated. They are not only related to possible morbidity and mortality, but also impose a significant economic burden on both society and the individual (patient, family, health care workers) in terms of consumption of health care resources and lost productivity, and in many cases avoidable pain and suffering. However, to prevent adverse events, it may take many years for the proposed rule to achieve its full beneficial effects, and it will remain a challenge to track the effect of the proposed rule on the patient population and society, generally.

It may be possible to measure improvements in patient safety in general descriptive terms regarding improved health outcomes. However, it is more difficult to translate such improvements to direct monetary savings or outcome measures that can be integrated into a single numerical index (e.g., units of health improvement, years of life gained). By analyzing patient safety event information, PSOs will be able to identify patterns of failures in the health care system and propose measures to eliminate patient safety risks and hazards as a means to improve patient outcomes. As more information is learned about patient safety events through data collection by the PSOs, the care delivery environment can be redesigned to prevent adverse events in the future. However, PSOs will not have the necessary authority to implement recommended changes to improve patient safety in providers' health care delivery organizations. It will be up to the providers themselves to bring about the changes that will result in a reduction in adverse events and a resultant improvement in the quality of care delivered.

The submission of more comprehensive information by health care providers regarding patient risks and hazards will likely increase the understanding of the factors that contribute to events that adversely affect patients. The expected benefit of this information would be improvements in patient safety event reports and analyses, which would translate to better patient outcomes and possible economic savings attributable to the more efficient use of health care services. Due to the uncertainty of the benefits and costs associated with the proposed rule as delineated above, it is then possible only to make general estimates of the monetary values of expected improvements in patient outcomes, that is, savings to the healthcare system.

We can estimate monetized benefits by referring to the Institute of Medicine report, To Err Is Human,[26] which estimates total national costs of preventable adverse events to be between $17 billion and $29 billion, of which direct health care costs represent over one-half (totaling between $8.5 billion and $14.5 billion). Based on the assumption that PSOs may be able to reduce the preventable adverse events by between one percent and three percent within their first five years of operation, this reduction would amount to be between $85 million—$145 million in savings at the 1 percent level if the whole nation were affected, and $255 million—$435 million at the 3 percent level, if the whole nation were affected. Applying a median figure from the Institute of Medicine range to PSOs, based on an increasing impact from 1%–3% as it grows over the first five

[23] Institute of Medicine, *"To Err Is Human: Building a Safer Health System",* 1999.

[24] Brennan TA, Leape LL, Laird NM, *et al.* Incidence of Adverse Events and Negligence in Hospitalized Patients. *New England Journal of Medicine.* 1991. 324: 370–76.

[25] Thomas EJ, Studdert DM, Burstin HR, *et al.* Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. *Medical Care.* 2000. 38: 261–71.

[26] Corrigan, J. M., Donaldson, M. S., Kohn, L. T., McKay, T., Pike, K. C., for the Committee on Quality of Health Care in America. *To Err Is Human: Building a Safer Health System.* Washington, DC: National Academy Press; 2000.

years, we see progressively growing savings as shown in Table 4. It should be noted that we are estimating savings by assuming a percentage reduction of adverse events from the overall occurrence rate delineated by the Institute of Medicine report. We are not tying the estimated reduction to those events specifically reported to PSOs. Events that have already occurred do not represent a potential for savings. The presumption behind the estimated savings is that the reporting, analysis, and institution of ameliorating policies and procedures will result in fewer adverse events going forward because of such PSO activities.

TABLE 4.—TOTAL ESTIMATED COST SAVINGS BY PERCENT REDUCTION IN ADVERSE EVENTS: 2008–2012 *

Year	2008	2009	2010	2011	2012
Hospital Penetration Rate	10%	40%	60%	75%	85%.
Percent Reduction in Adverse Events	1%	1.5%	2%	2.5%	3%.
Savings	$11.5 M	$69 M	$138 M	$215.625 M	$293.25 M.

* Source: Baseline figures from IOM Report, To Err Is Human, on total national health care costs associated with preventable adverse events (between 8.5 billion and 14.5 billion). Year 1 estimates are based on mid-point figures.

It is assumed that when the proposed rule is implemented, it will have a beneficial effect on patient outcomes. Eliminating adverse events would help to ensure the greatest value possible from the billions of dollars spent on medical care in the United States.[27] AHRQ concludes that the potential benefits of the Patient Safety Act—which encourages hospitals, doctors, and other health care providers to work voluntarily with PSOs by reporting of health care errors and enabling PSOs to analyze them to improve health care quality and safety—would justify the costs of the proposed rule.

During the first five operational years of PSOs, we calculated the net benefits based on total costs and benefits. (See Table 5.) We estimate that costs of implementing the Patient Safety Act will reach break-even after 2010 and provide progressively greater benefits thereafter.

TABLE 5.—NET BENEFITS: 2008–2012

Year	2008	2009	2010	2011	2012
Total Benefits	$11.5 M	$69 M	$138 M	$215.625 M	$293.25 M.
Total Costs	$68.9 M	$122.1 M	$167.8 M	$179.0 M	$186.5 M.
Net Benefits	($57.4) M	($53.1) M	($29.8) M	$36.625 M	$106.75 M.
Discounted net present value at 3%	($55.7) M	($50.0) M	($27.3) M	$32.5 M	$92.1 M.
Discounted net present value at 7%	($53.6) M	($46.4) M	($24.3) M	$27.9 M	$76.1 M.

Confidentiality Rule

The confidentiality provisions are included in the Patient Safety Act to encourage provider participation. Without such protections, providers will be reluctant to participate in the expanded reporting and analysis of patient safety events, and low participation will severely inhibit the opportunity to reap the benefits from efforts to improve patient safety. The proposed rule requires any holder of patient safety work product to maintain its confidentiality but, with the exception of PSOs, the appropriate security measures are left to the holder's discretion. Proposed § 3.106 establishes a security framework that PSOs must address but, even then, PSOs are given discretion to establish the specific security standards most appropriate to their organization. Violation of the confidentiality provisions under the proposed rule creates a risk of liability for a substantial civil money penalty. If a person makes a knowing or reckless disclosure in violation of the confidentiality provisions, that person will be subject to the enforcement process, and subject to costs including participation in an investigation and payment of a civil money penalty, if imposed.

While participating providers may incur some costs associated with maintaining the confidentiality of patient safety work product (e.g., developing policies/procedures to keep information confidential, safeguarding the information, training staff, etc.), those activities and associated costs are not required by the proposed rule and are likely minimal in light of existing procedures to meet existing requirements on providers to maintain sensitive information as confidential. We are proposing a scheme that places the least possible amount of regulatory burden on participants while simultaneously ensuring that the confidentiality provisions are effectively implemented and balanced with the objective of encouraging the maximum amount of participation possible. We were mindful of not placing unnecessary regulatory requirements on participating entities because this is a voluntary initiative, and we did not want entities interested in participating to forego participation because of concerns about the associated risk of liability for civil money penalties.

Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the Patient Safety Act enables a broad spectrum of entities—public, private, for-profit, and not-for-profit—to seek certification as a PSO, there may be many different types of organizations interested in becoming certified as a PSO that would be affected by the proposed rule. The proposed rule minimizes possible barriers to entry and creates a review process that is both simple and quick. As a result, AHRQ expects that a broad range of health care provider systems, medical specialty societies, and provider-based membership organizations will seek listing as a PSO by the Secretary.

AHRQ preliminarily determines that the proposed rule does not have a

[27] Corrigan, J. M., Donaldson, M. S., Kohn, L. T., McKay, T., Pike, K. C., for the Committee on Quality of Health Care in America. *To Err Is Human: Building a Safer Health System.* Washington, DC: National Academy Press; 2000.

significant impact on small businesses because it does not impose a mandatory regulatory burden, and because the Department has made a significant effort to promulgate regulations that are the minimum necessary to interpret and implement the law. As stated previously, working with PSOs is completely voluntary; the proposed rule provides benefits in the form of legal protections that are expected to outweigh the cost of participation from the perspective of participating providers. AHRQ believes that the proposed rule will not have a significant impact on a substantial number of small entities because the proposed rules do not place small entities at a significant competitive disadvantage to large entities. AHRQ does not anticipate that there will be a disproportional effect on profits, costs, or net revenues for a substantial number of small entities. The proposed rule will not significantly reduce profit for a substantial number of small entities.

Impacts on Small Entities

1. The Need for and the Objectives of the Proposed Rule

The proposed rule establishes the authorities, processes, and requirements necessary to implement the Patient Safety Act, sections 921–926 of the Public Health Service Act, 42 U.S.C. 299b–21 to 299b–26. The proposed rules seek to establish a streamlined process for the Department to accept certification by entities seeking to become PSOs. Under the proposal, PSOs will be available voluntarily to enter into arrangements with health care providers and provide expert advice regarding the causes and prevention of adverse patient safety events. Information collected or developed by a health care provider or PSO, and reported to or by a PSO, that relate to a patient safety event would become privileged and confidential. Related deliberations would also be protected. Persons who breached the confidentiality provisions of the rule could be subject to civil money penalties of up to $10,000.

2. Description and Estimate of the Number of Small Entities Affected

For purposes of the Regulatory Flexibility Act, small entities include small businesses, non-profit organizations, and government jurisdictions. Most hospitals and many other health care providers and suppliers are small entities, either because they are nonprofit organizations or because they generate revenues of $6.5 million to $31.5 million in any one year. Individuals and States are not included in the definition of a small entity. The proposed rule would affect most hospitals, and other health care delivery entities, plus all small entities that are interested in becoming certified PSOs. Based on various stakeholder meetings, AHRQ estimates that approximately 50–100 entities may be interested in becoming listed as PSOs during the first three years following publication of the final rule. This figure is likely to stabilize over time, as some new PSOs form and some existing PSOs cease operations.

3. Impact on Small Entities

AHRQ believes that the proposed rule will not have a significant impact on a substantial number of small provider or PSO entities because the proposed rule does not place a substantial number of small entities at a significant competitive disadvantage to large entities. AHRQ does not anticipate that there will be a disproportional effect on profits, costs, or net revenues for a substantial number of small entities. The proposed rule will not significantly reduce profit for a substantial number of small entities. In fact, when fully implemented, we expect that the benefits and/or provider savings will outweigh the costs.

Compliance requirements for small entities under this proposed rule are the same as those described above for other affected entities. AHRQ has proposed only those regulations that are necessary to comply with provisions and goals of the Patient Safety Act, with the objective of encouraging the maximum participation possible. The proposed rule was written to minimize the regulatory and economic burden on any entity that seeks to be listed as a PSO by the Secretary, regardless of size. It is impossible for AHRQ to develop alternatives to the proposed rule for small entities, as the proposed rule must adhere to statutory requirements. For example, the proposed rule requires confidentiality and privilege protections and places the least amount of regulatory burden on participating players—while simultaneously ensuring that the goals of confidentiality are effectively implemented—with the objective of encouraging the maximum participation possible. In addition, the proposed rule was written recognizing that many providers will be HIPAA covered entities, and many PSOs will be business associates, which entails certain obligations under the HIPAA Privacy Rule. Thus, this proposed rule is coordinated with existing law, to minimize the burden of compliance.

AHRQ believes that the proposed rule will not have a significant impact on small providers. The proposed rule does not impose any costs directly on providers, large or small, that choose to work with a PSO. To the extent that providers hold patient safety work product, they must prevent impermissible disclosures; however, the proposed rule does not establish requirements for how providers must meet this requirement.

Finally, it is the statutory and supporting regulatory guarantee of the confidentiality of the reporting of adverse events that will enable PSOs to operate and perform their function. Thus, while the compliance costs in the form of start-up operational costs may be substantial, the benefits that will be generated as a result of these costs will exceed the actual costs, as illustrated in Table 5.

The Secretary certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 42 CFR Part 3

Administrative practice and procedure, Civil money penalty, Confidentiality, Conflict of interests, Courts, Freedom of information, Health, Health care, Health facilities, Health insurance, Health professions, Health records, Hospitals, Investigations, Law enforcement, Medical research, Organization and functions, Patient, Patient safety, Privacy, Privilege, Public health, Reporting and recordkeeping requirements, Safety, State and local governments, Technical assistance.

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend Title 42 of the Code of Federal Regulations by adding a new part 3 to read as follows:

PART 3—PATIENT SAFETY ORGANIZATIONS AND PATIENT SAFETY WORK PRODUCT

Subpart A—General Provisions

Sec.

Subpart B—PSO Requirements and Agency Procedures

Authority: 42 U.S.C. 216, 299b–21 through 299b–26; 42 U.S.C. 299c–6

Subpart A—General Provisions

§ 3.10 Purpose.

The purpose of this Part is to implement the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109–41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 *et seq.*) by adding sections 921 through 926, 42 U.S.C. 299b–21 through 299b–26.

§ 3.20 Definitions.

As used in this Part, the terms listed alphabetically below have the meanings set forth as follows:

AHRQ stands for the Agency for Healthcare Research and Quality in HHS.

ALJ stands for an Administrative Law Judge of HHS.

Board means the members of the HHS Departmental Appeals Board, in the Office of the Secretary, who issue decisions in panels of three.

Bona fide contract means:

(1) A written contract between a provider and a PSO that is executed in good faith by officials authorized to execute such contract; or

(2) A written agreement (such as a memorandum of understanding or equivalent recording of mutual commitments) between a Federal, State, Local, or Tribal provider and a Federal, State, Local, or Tribal PSO that is executed in good faith by officials authorized to execute such agreement.

Complainant means a person who files a complaint with the Secretary pursuant to § 3.306.

Component organization means an entity that is either:

(1) A unit or division of a corporate organization or of a multi-organizational enterprise; or

(2) A separate organization, whether incorporated or not, that is owned, managed or controlled by one or more other organization(s), i.e., its parent organization(s).

Component PSO means a PSO listed by the Secretary that is a component organization.

Confidentiality provisions means for purposes of Subparts C and D, any requirement or prohibition concerning confidentiality established by section 921 and 922(b), (d), (g) and (i) of the Public Health Service Act, 42 U.S.C. 299b–21, 299b–22(b)–(d), (g) and (i) and the provisions, at §§ 3.206 and 3.208, that implement the statutory prohibition on disclosure of identifiable patient safety work product.

Disclosure means the release, transfer, provision of access to, or divulging in any other manner of patient safety work product by a person holding the patient safety work product to another.

Entity means any organization or organizational unit, regardless of whether the organization is public, private, for-profit, or not-for-profit.

Group health plan means employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 (ERISA)) to the extent that the plan provides medical care (as defined in paragraph (2) of section 2791(a) of the Public Health Service Act, including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

Health insurance issuer means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in 42 U.S.C. 300gg–91(b)(3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of 29 U.S.C. 1144(b)(2)). The term does not include a group health plan.

Health maintenance organization means:

(1) A Federally qualified health maintenance organization (HMO) (as defined in 42 U.S.C. 300e(a)),

(2) An organization recognized under State law as a health maintenance organization, or

(3) A similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

HHS stands for the United States Department of Health and Human Services.

HIPAA Privacy Rule means the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), at 45 CFR Part 160 and Subparts A and E of Part 164.

Identifiable patient safety work product means patient safety work product that:

(1) Is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in, or are responsible for, activities that are a subject of the work product;

(2) Constitutes individually identifiable health information as that term is defined in the HIPAA Privacy Rule at 45 CFR 160.103; or

(3) Is presented in a form and manner that allows the identification of an individual who in good faith reported information directly to a PSO or to a provider with the intention of having the information reported to a PSO (''reporter'').

Nonidentifiable patient safety work product means patient safety work product that is not identifiable patient safety work product in accordance with the nonidentification standards set forth at § 3.212.

OCR stands for the Office for Civil Rights in HHS.

Parent organization means an entity that, alone or with others, either owns a provider entity or a component organization, or has the authority to control or manage agenda setting, project management, or day-to-day operations, or the authority to review and override decisions of a component organization.

Patient Safety Act means the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109–41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 *et seq.*) by inserting a new Part C, sections 921 through 926, which are codified at 42 U.S.C. 299b–21 through 299b–26.

Patient safety activities means the following activities carried out by or on behalf of a PSO or a provider:

(1) Efforts to improve patient safety and the quality of health care delivery;

(2) The collection and analysis of patient safety work product;

(3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;

(4) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;

(5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product;

(6) The provision of appropriate security measures with respect to patient safety work product;

(7) The utilization of qualified staff; and

(8) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

Patient safety evaluation system means the collection, management, or analysis of information for reporting to or by a PSO.

Patient safety organization (PSO) means a private or public entity or component thereof that currently is listed as a PSO by the Secretary in accordance with Subpart B. A health insurance issuer or a component organization of a health insurance issuer may not be a PSO. See also the exclusion in proposed § 3.102 of this Part.

Patient safety work product (PSWP).

(1) Except as provided in paragraph (2) of this definition, patient safety work product means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material)

(i)(A) Which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO; or

(B) Are developed by a PSO for the conduct of patient safety activities; and which could improve patient safety, health care quality, or health care outcomes; or

(ii) Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

(2)(i) Patient safety work product does not include a patient's medical record, billing and discharge information, or any other original patient or provider information; nor does it include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered patient safety work product.

(ii) Nothing in this part shall be construed to limit information that is not patient safety work product from being:

(A) Discovered or admitted in a criminal, civil or administrative proceeding;

(B) Reported to a Federal, State, local or tribal governmental agency for public health or health oversight purposes; or

(C) Maintained as part of a provider's recordkeeping obligation under Federal, State, local or tribal law.

Person means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Provider means:

(1) An individual or entity licensed or otherwise authorized under State law to provide health care services, including—

(i) A hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office (includes a group practice), long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

(ii) A physician, physician assistant, registered nurse, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner;

(2) Agencies, organizations, and individuals within Federal, State, local, or Tribal governments that deliver health care, organizations engaged as contractors by the Federal, State, local, or Tribal governments to deliver health care, and individual health care practitioners employed or engaged as contractors by the Federal State, local, or Tribal governments to deliver health care; or

(3) A parent organization that has a controlling interest in one or more entities described in paragraph (1)(i) of this definition or a Federal, State, local, or Tribal government unit that manages or controls one or more entities described in (1)(i) or (2) of this definition.

Research has the same meaning as the term is defined in the HIPAA Privacy Rule at 45 CFR 164.501.

Respondent means a provider, PSO, or responsible person who is the subject of a complaint or a compliance review.

Responsible person means a person, other than a provider or a PSO, who has possession or custody of identifiable patient safety work product and is subject to the confidentiality provisions.

Workforce means employees, volunteers, trainees, contractors, and other persons whose conduct, in the performance of work for a provider, PSO or responsible person, is under the direct control of such provider, PSO or responsible person, whether or not they are paid by the provider, PSO or responsible person.

Subpart B—PSO Requirements and Agency Procedures

§ 3.102 Process and requirements for initial and continued listing of PSOs.

(a) *Eligibility and process for initial and continued listing.*

(1) *Submission of Certification.* Any entity, except as specified in paragraph (a)(2) of this section, may request from the Secretary an initial or continued listing as a PSO by submitting a completed certification form that meets the requirements of this section, in accordance with the submission requirements at § 3.112. An individual with authority to make commitments on behalf of the entity seeking listing will be required to acknowledge each of the certification requirements, attest that the entity meets each requirement, provide contact information for the entity, and certify that the PSO will promptly notify the Secretary during its period of listing if it can no longer comply with any of the criteria in this section.

(2) *Restrictions on certain entities.* Entities that may not seek listing as a PSO include: health insurance issuers or components of health insurance issuers. Any other entity, public or private, that conducts regulatory oversight of health care providers, such as accreditation or licensure, may not seek listing, except that a component of such an entity may seek listing as a component PSO. An applicant completing the required certification forms described in paragraph (a)(1) of this section will be required to attest that the entity is not subject to the restrictions of this paragraph.

(b) *Fifteen general PSO certification requirements.* The certifications submitted to the Secretary in accordance with paragraph (a)(1) of this section must conform to the following 15 requirements:

(1) *Required certification regarding eight patient safety activities.* An entity seeking initial listing as a PSO must certify that it has written policies and procedures in place to perform each of the eight patient safety activities,

defined in § 3.20. Such policies and procedures will provide for compliance with the confidentiality provisions of subpart C of this part and the appropriate security measures required by § 3.106 of this subpart. A PSO seeking continued listing must certify that it is performing, and will continue to perform, each of the patient safety activities, and is and will continue to comply with subpart C of this part and the security requirements referenced in the preceding sentence.

(2) *Required certification regarding seven PSO criteria.* In its initial certification submission, an entity must also certify that it will comply with the additional seven requirements in paragraphs (b)(2)(i) through (b)(2)(vii) of this section. A PSO seeking continued listing must certify that it is complying with, and will continue to comply with, the requirements of this paragraph.

(i) The mission and primary activity of a PSO must be to conduct activities that are to improve patient safety and the quality of health care delivery.

(ii) The PSO must have appropriately qualified workforce members, including licensed or certified medical professionals.

(iii) The PSO, within the 24-month period that begins on the date of its initial listing as a PSO, and within each sequential 24-month period thereafter, must have entered into 2 bona fide contracts, each of a reasonable period of time, each with a different provider for the purpose of receiving and reviewing patient safety work product.

(iv) The PSO is not a health insurance issuer, and is not a component of a health insurance issuer.

(v) The PSO must make disclosures to the Secretary as required under § 3.102(d), in accordance with § 3.112 of this subpart.

(vi) To the extent practical and appropriate, the PSO must collect patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.

(vii) The PSO must utilize patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

(c) *Additional certifications required of component organizations.* In addition to meeting the 15 general PSO certification requirements of paragraph (b) of this section, an entity seeking initial listing that is a component of another organization or enterprise must certify that it will comply with the requirements of paragraphs (c)(1) through (c)(3) of this section. A component PSO seeking continued listing must certify that it is complying with, and will continue to comply with, the requirements of this paragraph.

(1) *Separation of patient safety work product.*

(i) A component PSO must:

(A) Maintain patient safety work product separately from the rest of the parent organization(s) of which it is a part; and

(B) Not have a shared information system that could permit access to its patient safety work product to an individual(s) in, or unit(s) of, the rest of the parent organization(s) of which it is a part.

(ii) Notwithstanding the requirements of paragraph (c)(1)(i) of this section, a component PSO may provide access to identifiable patient safety work product to an individual(s) in, or a unit(s) of, the rest of the parent organization(s) of which it is a part if the component PSO enters into a written agreement with such individuals or units that requires that:

(A) The component PSO will only provide access to identifiable patient safety work product to enable such individuals or units to assist the component PSO in its conduct of patient safety activities, and

(B) Such individuals or units that receive access to identifiable patient safety work product pursuant to such written agreement will only use or disclose such information as specified by the component PSO to assist the component PSO in its conduct of patient safety activities, will take appropriate security measures to prevent unauthorized disclosures and will comply with the other certifications the component has made pursuant to paragraphs (c)(2) and (c)(3) of this section regarding unauthorized disclosures and conflicts with the mission of the component PSO.

(2) *Nondisclosure of patient safety work product.* A component PSO must require that members of its workforce and any other contractor staff, or individuals in, or units of, its parent organization(s) that receive access in accordance with paragraph (c)(1)(ii) of this section to its identifiable patient safety work product, not be engaged in work for the parent organization(s) of which it is a part, if the work could be informed or influenced by such individuals' knowledge of identifiable patient safety work product, except for individuals whose other work for the rest of the parent organization(s) is solely the provision of clinical care.

(3) *No conflict of interest.* The pursuit of the mission of a component PSO must not create a conflict of interest with the rest of the parent organization(s) of which it is a part.

(d) *Required notifications.* PSOs must meet the following notification requirements:

(1) *Notification regarding PSO compliance with the minimum contract requirement.* No later than 45 calendar days prior to the last day of the applicable 24-month assessment period, specified in paragraph (b)(2)(iii) of this section, the Secretary must receive from a PSO a certification that states whether it has met the requirement of that paragraph regarding two bona fide contracts, in accordance with § 3.112 of this subpart.

(2) *Notification regarding a PSO's relationships with its contracting providers.* A PSO must submit to the Secretary a disclosure statement, in accordance with § 3.112 of this subpart, regarding its relationships with each provider with which the PSO has a contract pursuant to the Patient Safety Act if the circumstances described in either paragraph (d)(2)(i) or (d)(2)(ii) of this section are applicable. The Secretary must receive a disclosure statement within 45 days of the date on which a PSO enters a contract with a provider if the circumstances are met on the date the contract is entered. During the contract period, if a PSO subsequently enters one or more relationships with a contracting provider that create the circumstances described in paragraph (d)(2)(i) of this section or a provider exerts any control over the PSO of the type described in paragraph (d)(2)(ii) of this section, the Secretary must receive a disclosure statement from the PSO within 45 days of the date that the PSO entered each new relationship or of the date on which the provider imposed control of the type described in paragraph (d)(2)(ii).

(i) Taking into account all relationships that the PSO has with the provider, other than the bona fide contract entered into pursuant to the Patient Safety Act, the PSO must fully disclose any other contractual, financial, or reporting relationships described below that it has with that provider.

(A) Contractual relationships which are not limited to relationships based on formal contracts but also encompass relationships based on any oral or written agreement or any arrangement that imposes responsibilities on the PSO.

(B) Financial relationships including any direct or indirect ownership or investment relationship between the PSO and the contracting provider, shared or common financial interests or direct or indirect compensation

arrangement, whether in cash or in-kind.

(C) Reporting relationships including any relationship that gives the provider access to information or control, directly or indirectly, over the work of the PSO that is not available to other contracting providers.

(ii) Taking into account all relationships that the PSO has with the provider, the PSO must fully disclose if it is not independently managed or controlled, or if it does not operate independently from, the contracting provider. In particular, the PSO must further disclose whether the contracting provider has exercised or imposed any type of management control that could limit the PSO's ability to fairly and accurately perform patient safety activities and fully describe such control(s).

(iii) PSOs may also describe or include in their disclosure statements, as applicable, any agreements, stipulations, or procedural safeguards that have been created to protect the ability of the PSO to operate independently or information that indicates the limited impact or insignificance of its financial, reporting, or contractual relationships with a contracting provider.

§ 3.104 Secretarial actions.

(a) *Actions in response to certification submissions for initial and continued listing as a PSO.* (1) In response to an initial or continued certification submission by an entity, pursuant to the requirements of § 3.102 of this subpart, the Secretary may—

(i) Accept the certification submission and list the entity as a PSO, or maintain the listing of a PSO, if the Secretary determines that the entity meets the applicable requirements of the Patient Safety Act and this subpart;

(ii) Deny acceptance of a certification submission and, in the case of a currently listed PSO, remove the entity from the list if the entity does not meet the applicable requirements of the Patient Safety Act and this subpart; or

(iii) Condition the listing of an entity, or continued listing of a PSO, following a determination made pursuant to paragraph (c) of this section.

(2) *Basis of determination.* In making a determination regarding listing, the Secretary will consider the certification submission; any prior actions by the Secretary regarding the entity or PSO including delisting; any history of or current non-compliance by the entity or the PSO with statutory or regulatory requirements or requests from the Secretary; the relationships of the entity or PSO with providers; and any findings made by the Secretary in accordance with paragraph (c) of this section.

(3) *Notification.* The Secretary will notify in writing each entity of action taken on its certification submission for initial or continued listing. The Secretary will provide reasons when an entity's certification is conditionally accepted and the entity is conditionally listed, when an entity's certification is not accepted and the entity is not listed, or when acceptance of its certification is revoked and the entity is delisted.

(b) *Actions regarding PSO compliance with the minimum contract requirement.* When the Secretary receives notification required by § 3.102(d)(1) of this subpart that the PSO has met the minimum contract requirement, the Secretary will acknowledge in writing receipt of the notification and add information to the list established pursuant to paragraph (d) of this section stating that the PSO has certified that it has met the requirement. If the PSO states that it has not yet met the minimum contract requirement, or if notice is not received by the date specified in § 3.102(d)(1) of this subpart, the Secretary will issue to the PSO a notice of a preliminary finding of deficiency as specified in § 3.108(a)(2) and establish a period for correction that extends until midnight of the last day of the PSO's applicable 24-month period of assessment. Immediately thereafter, if the requirement has not been met, the Secretary will provide the PSO a written notice of proposed revocation and delisting in accordance with § 3.108(a)(3) of this subpart.

(c) *Actions regarding required disclosures by PSOs of relationships with contracting providers.* The Secretary will review and make findings regarding each disclosure statement submitted by a PSO, pursuant to § 3.102(d)(2) of this subpart, regarding its relationships with contracting provider(s), determine whether such findings warrant action regarding the listing of the PSO, and make the findings public.

(1) *Basis of findings regarding PSO disclosure statements.* In reviewing disclosure statements, submitted pursuant to § 3.102(d)(2) of this subpart, the Secretary will consider the nature, significance, and duration of the disclosed relationship(s) between the PSO and the contracting provider and will determine whether the PSO can fairly and accurately perform the required patient safety activities.

(2) *Determination by the Secretary.* Based on the Secretary's review and findings, he may choose to take any of the following actions:

(i) For an entity seeking an initial or continued listing, the Secretary may list or continue the listing of an entity without conditions, list the entity subject to conditions, or deny the entity's certification for initial or continued listing; or

(ii) For a listed PSO, the Secretary may determine that the entity will remain listed without conditions, continue the entity's listing subject to conditions, or remove the entity from listing.

(3) *Release of disclosure statements and Secretarial findings.*

(i) Subject to paragraph (c)(3)(ii) of this section, the Secretary will make disclosure statements available to the public along with related findings that are made available in accordance with paragraph (c) of this section.

(ii) The Secretary may withhold information that is exempt from public disclosure under the Freedom of Information Act.

(d) *Maintaining a list of PSOs.* The Secretary will compile and maintain a publicly available list of entities whose certifications as PSOs have been accepted. The list will include contact information for each entity, a copy of all certification forms and disclosure statements submitted by each entity, the effective date of the PSO's listing, and information on whether a PSO has certified that it has met the two-contract requirement. The list also will include a copy of the Secretary's findings regarding each disclosure statement submitted by an entity, information describing any related conditions that have been placed by the Secretary on the listing of an entity as a PSO, and other information that this Subpart states may be made public. AHRQ will establish a PSO Web site (or a comparable future form of public notice) and may post the list on this Web site.

(e) *Three-year period of listing.* (1) The period of listing of a PSO will be for a three-year period, unless the listing is revoked or relinquished prior to the expiration of the three-year period, in accordance with § 3.108 of this subpart.

(2) The Secretary will send a written notice of imminent expiration to a PSO at least 45 calendar days prior to the date on which its three-year period of listing expires if the Secretary has not received a certification for continued listing.

(f) *Effective dates of Secretarial actions.* Unless otherwise stated, the effective date of each action by the Secretary pursuant to this subpart will be specified in the written notice of such action that is sent to the entity. When the Secretary sends a notice that addresses acceptance or revocation of an

entity's certifications or voluntary relinquishment by an entity of its status as a PSO, the notice will specify the effective date and time of listing or delisting.

§ 3.106 Security requirements.

(a) *Application.* A PSO must provide security for patient safety work product that conforms to the security requirements of paragraph (b) of this section. These requirements must be met at all times and at any location at which the PSO, its workforce members, or its contractors hold patient safety work product.

(b) *Security framework.* PSOs must consider the following framework for the security of patient safety work product. The framework includes four elements: security management, separation of systems, security monitoring and control, and system assessment. To address the four elements of this framework, a PSO must develop appropriate and scalable security standards, policies, and procedures that are suitable for the size and complexity of its organization.

(1) *Security management.* A PSO must address:

(i) Maintenance and effective implementation of written policies and procedures that conform to the requirements of this section to protect the confidentiality, integrity, and availability of the patient safety work product that is processed, stored, and transmitted; and to monitor and improve the effectiveness of such policies and procedures, and

(ii) Training of the PSO workforce and PSO contractors who access or hold patient safety work product regarding the requirements of the Patient Safety Act, this Part, and the PSO's policies and procedures regarding the confidentiality and security of patient safety work product.

(2) *Separation of Systems.* A PSO must address:

(i) Maintenance of patient safety work product, whether in electronic or other media, physically and functionally separate from any other system of records;

(ii) Protection of the media, whether in electronic, paper, or other format, that contain patient safety work product, limiting access to authorized users, and sanitizing and destroying such media before disposal or release for reuse; and

(iii) Physical and environmental protection, to control and limit physical and virtual access to places and equipment where patient safety work product is stored or used.

(3) *Security control and monitoring.* A PSO must address:

(i) Identification of those authorized to have access to patient safety work product and an audit capacity to detect unlawful, unauthorized, or inappropriate access to patient safety work product, and

(ii) Measures to prevent unauthorized removal, transmission or disclosure of patient safety work product.

(4) *Security assessment.* A PSO must address:

(i) Periodic assessments of security risks and controls, as determined appropriate by the PSO, to establish if its controls are effective, to correct any deficiency identified, and to reduce or eliminate any vulnerabilities.

(ii) System and communications protection, to monitor, control, and protect PSO uses, communications, and transmissions involving patient safety work product to and from providers and any other responsible persons.

§ 3.108 Correction of deficiencies, revocation, and voluntary relinquishment.

(a) *Process for correction of a deficiency and revocation*—(1) *Circumstances leading to revocation.* The Secretary may revoke his acceptance of an entity's certification and delist the entity as a PSO if he determines—

(i) The PSO is not fulfilling the certifications it made to the Secretary that are set forth in § 3.102 of this subpart;

(ii) The PSO has not timely notified the Secretary that it has met the two contract requirement, as required by § 3.102(d)(1) of this subpart;

(iii) The Secretary, based on a PSO's disclosures made pursuant to § 3.102(d)(2) of this subpart, makes a public finding that the entity cannot fairly and accurately perform the patient safety activities of a PSO; or

(iv) The PSO is not in compliance with any other provision of the Patient Safety Act or this Part.

(2) *Notice of preliminary finding of deficiency and establishment of an opportunity for correction of a deficiency.* (i) If the Secretary determines that a PSO is not in compliance with its obligations under the Patient Safety Act or this Subpart, the Secretary must send a PSO written notice of the preliminary finding of deficiency. The notice must state the actions or inactions that encompass the deficiency finding, outline the evidence that the deficiency exists, specify the possible and/or required corrective actions that must be taken, and establish a date by which the deficiency must be corrected. The Secretary may specify in the notice the level of documentation required to demonstrate that the deficiency has been corrected.

(ii) The notice of a preliminary finding of deficiency is presumed received five days after it is sent, absent evidence of the actual receipt date. If a PSO does not submit evidence to the Secretary within 14 calendar days of actual or constructive receipt of such notice, whichever is longer, which demonstrates that the preliminary finding is factually incorrect, the preliminary finding will be the basis for a finding of deficiency.

(3) *Determination of correction of a deficiency.* (i) Unless the Secretary specifies another date, the Secretary must receive documentation to demonstrate that the PSO has corrected the deficiency no later than five calendar days following the last day of the correction period, that is specified by the Secretary in the notice of preliminary finding of deficiency.

(ii) In making a determination regarding the correction of any deficiency, the Secretary will consider the documentation submitted by the PSO, the findings of any site visit that he determines is necessary or appropriate, recommendations of program staff, and any other information available regarding the PSO that the Secretary deems appropriate and relevant to the PSO's implementation of the terms of its certification.

(iii) After completing his review, the Secretary may make one of the following determinations:

(A) The action(s) taken by the PSO have corrected any deficiency, in which case the Secretary will withdraw the notice of deficiency and so notify the PSO;

(B) The PSO has acted in good faith to correct the deficiency but the Secretary finds an additional period of time is necessary to achieve full compliance and/or the required corrective action specified in the notice of a preliminary finding of deficiency needs to be modified in light of the experience of the PSO in attempting to implement the corrective action, in which case the Secretary will extend the period for correction and/or modify the specific corrective action required; or

(C) The PSO has not completed the corrective action because it has not acted with reasonable diligence or speed to ensure that the corrective action was completed within the allotted time, in which case the Secretary will issue to the PSO a notice of proposed revocation and delisting.

(iv) When the Secretary issues a written notice of proposed revocation and delisting, the notice will specify the

deficiencies that have not been timely corrected and will detail the manner in which the PSO may exercise its opportunity to be heard in writing to respond to the deficiencies specified in the notice.

(4) *Opportunity to be heard in writing following a notice of proposed revocation and delisting.* The Secretary will afford a PSO an opportunity to be heard in writing, as specified in paragraph (a)(4)(i) of this section, to provide a substantive response to the deficiency finding(s) set forth in the notice of proposed revocation and delisting.

(i) The notice of proposed revocation and delisting is presumed received five days after it is sent, absent evidence of actual receipt. The Secretary will provide a PSO with a period of time, beginning with the date of receipt of the notice of proposed revocation and delisting of which there is evidence, or the presumed date of receipt if there is no evidence of earlier receipt, and ending at midnight 30 calendar days thereafter, during which the PSO can submit a substantive response to the deficiency findings in writing.

(ii) The Secretary will provide to the PSO rules of procedure governing the form or transmission of the written response to the notice of proposed revocation and delisting. The Rules may also be posted on the AHRQ PSO Web site or published in the **Federal Register**.

(iii) If a PSO does not submit a written response to the deficiency finding(s) within 30 calendar days of receipt of the notice of proposed revocation and delisting, the notice of proposed revocation becomes final as a matter of law and the basis for Secretarial action under paragraph (b)(1) of this section.

(5) *The Secretary's decision regarding revocation.* The Secretary will review the entire administrative record pertaining to a notice of proposed revocation and delisting and any written materials submitted by the PSO under paragraph (a)(4) of this section. The Secretary may affirm, reverse, or modify the notice of proposed revocation and delisting and will make a determination with respect to the continued listing of the PSO.

(b) *Revocation of the Secretary's acceptance of a PSO's certifications—(1) Establishing revocation for cause.* When the Secretary concludes, in accordance with a decision made under paragraph (a)(5) of this section, that revocation of the acceptance of a PSO's certification is warranted for its failure to comply with requirements of the Patient Safety Act or of this Subpart, the Secretary will establish the time and date for the prompt revocation and removal of the entity from the list of PSOs, so notify the PSO in writing, and provide the relevant public notice required by § 3.108(d) of this subpart.

(2) *Required notification of providers and status of data.* Within 15 days of being notified of the Secretary's action pursuant to paragraph (b)(1) of this section, an entity subject to paragraph (b)(1) of this section will submit to the Secretary confirmation that it has taken all reasonable actions to notify each provider, whose patient safety work product it collected or analyzed, of the Secretary's action(s). Confidentiality and privilege protections that applied to patient safety work product while the former PSO was listed continue to apply after the entity is removed from listing. Data submitted by providers to the former PSO within 30 calendar days of the date on which it is removed from the list of PSOs pursuant to paragraph (b)(1) of this section will have the same status as data submitted while the entity was still listed.

(3) *Disposition of patient safety work product and data.* Following revocation and delisting pursuant to paragraph (b)(1) of this section, the former PSO will take one or more of the following measures:

(i) Transfer such patient safety work product or data, with the approval of the source from which it was received, to a PSO that has agreed to receive such patient safety work product or data;

(ii) Return such work product or data to the source from which it was submitted; or

(iii) If returning such patient safety work product or data to its source is not practicable, destroy such patient safety work product or data.

(c) *Voluntary relinquishment*—(1) *Circumstances constituting voluntary relinquishment.* A PSO will be considered to have voluntarily relinquished its status as a PSO if the Secretary accepts a notification from a PSO that it wishes to relinquish voluntarily its listing as a PSO or the Secretary determines that an implied voluntary relinquishment has taken place because the period of listing of a PSO has expired without receipt of a timely submission of certifications for continued listing.

(2) *Notification of voluntary relinquishment.* A PSO's notification of voluntary relinquishment to the Secretary must include the following:

(i) An attestation that all reasonable efforts have been made, or will have been made by a PSO within 15 calendar days of this statement, to notify the sources from which it received patient safety work product or data of the PSO's intention to cease operations, to relinquish voluntarily its status as a PSO, to request that these other entities cease reporting or submitting any further information to the PSO as soon as possible, and inform them that any data submitted after the effective date and time of delisting, that the Secretary sets pursuant to paragraph (c)(3) of this section, will not be protected as patient safety work product under the Patient Safety Act based upon such submissions;

(ii) An attestation that the entity has established a plan, or within 15 calendar days of this statement, will have made all reasonable efforts to establish a plan, in consultation with the sources from which it received patient safety work product or data, that provides for the disposition of such patient safety work product or data consistent with, to the extent practicable, the statutory options for disposition of patient safety work product or data as set out in paragraphs (b)(3)(i) through (iii) of this section; and

(iii) Appropriate contact information for further communications from the Secretary.

(3) *Response to notification of voluntary relinquishment.* (i) After a PSO provides the notification required by paragraph (c)(2) of this section, the Secretary will respond in writing to the entity indicating whether the proposed voluntary relinquishment of its PSO status is accepted. If the voluntary relinquishment is accepted, the Secretary's response will indicate an effective date and time for the entity's removal from the list of PSOs and will provide public notice of the delisting, in accordance with § 3.108(d) of this subpart.

(ii) If the Secretary receives a notification of voluntary relinquishment during or immediately after revocation proceedings for cause under paragraphs (a)(4) and (a)(5) of this section, the Secretary, as a matter of discretion, may accept voluntary relinquishment in accordance with the preceding paragraph or decide not to accept the entity's proposed voluntary relinquishment and proceed with the revocation for cause and delisting pursuant to paragraph (b)(1) of this section.

(4) *Implied voluntary relinquishment.* (i) If the period of listing of a PSO lapses without timely receipt and acceptance by the Secretary of a certification seeking continued listing or timely receipt of a notification of voluntary relinquishment of its PSO status in accordance with paragraph (c)(2) of this section, the Secretary will determine that voluntary relinquishment has

occurred and will remove the entity from the list of PSOs effective as of midnight on the last day of its three-year period of listing. The Secretary will take reasonable measures to notify the entity of its delisting and will provide public notice of the delisting in accordance with § 3.108(d) of this subpart.

(ii) The Secretary will request in the notice to the entity that it make reasonable efforts to comply with the requirements of paragraph (c)(2) of this section with respect to notification, appropriate disposition of patient safety work product, and the provision of contact information to the Secretary.

(5) *Non-applicability of certain procedures and requirements.* (i) A decision by the Secretary to accept a request by a PSO to relinquish voluntarily its status as a PSO pursuant to paragraph (c)(2) of this section or a decision that voluntary relinquishment has occurred pursuant to paragraph (c)(4) of this section does not constitute a determination of a deficiency in PSO compliance with the Patient Safety Act or with this Subpart and no opportunity for corrective action by the PSO is required.

(ii) The procedures and requirements of § 3.108(a) of this subpart regarding deficiencies including the opportunity to be heard in writing, and those that are based upon determinations of the Secretary pursuant to § 3.108(b)(1) of this subpart are not applicable to determinations of the Secretary made pursuant to paragraph (c) of this section.

(d) *Public notice of delisting regarding removal from listing.* If the Secretary removes an entity from the list of PSOs following revocation of acceptance of the entity's certification pursuant to § 3.108(b)(1) of this subpart or following a determination of voluntary relinquishment pursuant to § 3.108(c)(3) or (c)(4) of this subpart, the Secretary will promptly publish in the **Federal Register** and on the AHRQ PSO Web site, or in a comparable future form of public notice, established pursuant to § 3.104(d) of this subpart, a notice of the actions taken and the effective dates.

§ 3.110 Assessment of PSO compliance.

The Secretary may request information or conduct announced or unannounced reviews of or site visits to PSOs, to assess or verify PSO compliance with the requirements of this subpart and for these purposes will be allowed to inspect the physical or virtual sites maintained or controlled by the PSO. The Secretary will be allowed to inspect and/or be given or sent copies of any PSO records deemed necessary and requested by the Secretary to implement the provisions of this subpart. Such PSO records may include patient safety work product in accordance with § 3.206(d) of this subpart.

§ 3.112 Submissions and forms.

(a) Forms referred to in this subpart may be obtained on the AHRQ PSO Web site or a comparable future form of public notice or by requesting them in writing by e-mail at *psimplement@ahrq.hhs.gov,* or by mail from the Agency for Healthcare Research and Quality, CQuIPS, PSO Liaison, 540 Gaither Road, Rockville, MD 20850. A form (including any required attachments) must be submitted in accordance with the accompanying instructions.

(b) Information submitted to AHRQ in writing, but not required to be on a form, and requests for information from AHRQ, may be submitted by mail or other delivery to the Agency for Healthcare Research and Quality, CQuIPS, PSO Liaison, 540 Gaither Road, Rockville, MD 20850, by facsimile at (301) 427–1341, or by e-mail at *psimplement@ahrq.hhs.gov.*

(c) If a submission to the Secretary is incomplete or additional information is needed to allow a determination to be made under this subpart, the submitter will be notified if any additional information is required.

Subpart C—Confidentiality and Privilege Protections of Patient Safety Work Product

§ 3.204 Privilege of Patient Safety Work Product

(a) *Privilege.* Notwithstanding any other provision of Federal, State, local, or tribal law and subject to paragraph (b) of this section and § 3.208 of this subpart, patient safety work product shall be privileged and shall not be:

(1) Subject to a Federal, State, local, or tribal civil, criminal, or administrative subpoena or order, including in a Federal, State, local, or tribal civil or administrative disciplinary proceeding against a provider;

(2) Subject to discovery in connection with a Federal, State, local, or tribal civil, criminal, or administrative proceeding, including in a Federal, State, local, or tribal civil or administrative disciplinary proceeding against a provider;

(3) Subject to disclosure pursuant to section 552 of Title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, local, or tribal law;

(4) Admitted as evidence in any Federal, State, local, or tribal governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or

(5) Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

(b) *Exceptions to privilege.* Privilege shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(1) Disclosure of relevant patient safety work product for use in a criminal proceeding, subject to the conditions at § 3.206(b)(1) of this subpart.

(2) Disclosure to the extent required to permit equitable relief subject to the conditions at § 3.206(b)(2) of this subpart.

(3) Disclosure pursuant to provider authorizations subject to the conditions at § 3.206(b)(3) of this subpart.

(4) Disclosure of non-identifiable patient safety work product subject to the conditions at § 3.206(b)(5) of this subpart.

(c) *Implementation and Enforcement of the Patient Safety Act.* Privilege shall not apply to (and shall not be construed to prohibit) disclosures of relevant patient safety work product to or by the Secretary if such patient safety work product is needed to investigate or determine compliance with this part or is needed in seeking or imposing civil money penalties, or in making or supporting PSO certification or listing decisions, under the Patient Safety Act.

§ 3.206 Confidentiality of Patient Safety Work Product.

(a) *Confidentiality.* Subject to paragraphs (b) through (e) of this section, and §§ 3.208 and 3.210 of this subpart, patient safety work product shall be confidential and shall not be disclosed.

(b) *Exceptions to confidentiality.* The confidentiality provisions shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(1) *Criminal proceedings.* Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an *in camera* determination that:

(i) Such patient safety work product contains evidence of a criminal act;

(ii) Such patient safety work product is material to the proceeding; and

(iii) Such patient safety work product is not reasonably available from any other source.

(2) *Equitable relief for reporters.* Disclosure of patient safety work

product to the extent required to permit equitable relief under section 922 (f)(4)(A) of the Public Health Service Act.

(3) *Authorized by identified providers.* (i) Disclosure of identifiable patient safety work product consistent with a valid authorization if such authorization is obtained from each provider identified in such work product prior to disclosure. A valid authorization must:

(A) Be in writing and signed by the provider from whom authorization is sought; and

(B) Contain sufficient detail to fairly inform the provider of the nature and scope of the disclosures being authorized;

(ii) A valid authorization must be retained by the disclosing entity for six years from the date of the last disclosure made in reliance on the authorization and made available to the Secretary upon request.

(4) *Patient safety activities*—(i) *Disclosure between a provider and a PSO.* Disclosure of patient safety work product for patient safety activities by a provider to a PSO or by a PSO to that disclosing provider.

(ii) *Disclosure to a contractor of a provider or a PSO.* A provider or a PSO may disclose patient safety work product for patient safety activities to an entity with which it has contracted to undertake patient safety activities on its behalf. A contractor receiving patient safety work product for patient safety activities may not further disclose patient safety work product, except to the entity with which it is contracted.

(iii) *Disclosure by a PSO to another PSO or by a provider to another provider.* Disclosure of patient safety work product for patient safety activities by a PSO to another PSO or to another provider that has reported to the PSO, or by a provider to another provider, provided:

(A) The following direct identifiers of any providers and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members of such providers are removed:

(*1*) Names;

(*2*) Postal address information, other than town or city, State and zip code;

(*3*) Telephone numbers;

(*4*) Fax numbers;

(*5*) Electronic mail addresses;

(*6*) Social security numbers or taxpayer identification numbers;

(*7*) Provider or practitioner credentialing or DEA numbers;

(*8*) National provider identification number;

(*9*) Certificate/license numbers;

(*10*) Web Universal Resource Locators (URLs);

(*11*) Internet Protocol (IP) address numbers;

(*12*) Biometric identifiers, including finger and voice prints; and

(*13*) Full face photographic images and any comparable images; and

(B) With respect to any individually identifiable health information in such patient safety work product, the direct identifiers listed at 45 CFR 164.514(e)(2) have been removed.

(5) *Disclosure of nonidentifiable patient safety work product.* Disclosure of nonidentifiable patient safety work product when patient safety work product meets the standard for nonidentification in accordance with § 3.212 of this subpart.

(6) *For research.* (i) Disclosure of patient safety work product to persons carrying out research, evaluation or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research.

(ii) If the patient safety work product disclosed pursuant to paragraph (b)(6)(i) of this section is by a HIPAA covered entity as defined at 45 CFR 160.103 and contains protected health information as defined by the HIPAA Privacy Rule at 45 CFR 160.103, such patient safety work product may only be disclosed under this exception in the same manner as would be permitted under the HIPAA Privacy Rule at 45 CFR 164.512(i).

(7) *To the Food and Drug Administration (FDA).*

(i) Disclosure by a provider of patient safety work product concerning an FDA-regulated product or activity to the FDA or to an entity required to report to the FDA concerning the quality, safety, or effectiveness of an FDA-regulated product or activity.

(ii) The FDA and any entity receiving patient safety work product pursuant to paragraph (b)(7)(i) of this section may only further disclose such patient safety work product for the purpose of evaluating the quality, safety, or effectiveness of that product or activity between each other, their contractors, and the disclosing provider. A contractor receiving patient safety work product pursuant to this paragraph may not further disclose patient safety work product, except to the entity from which it received the patient safety work product.

(8) *Voluntary disclosure to an accrediting body.*

(i) Voluntary disclosure by a provider of patient safety work product that identifies that provider to an accrediting body that accredits that provider. Such accrediting body may not further disclose such patient safety work product.

(ii) An accrediting body may not take an accrediting action against a provider based on a good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this Part. An accrediting body may not require a provider to reveal its communications with any PSO.

(9) *Business operations.* (i) Disclosure of patient safety work product by a provider or a PSO for business operations to attorneys, accountants, and other professionals. Such contractors may not further disclose patient safety work product, except to the entity from which they received the information.

(ii) Disclosure of patient safety work product for such other business operations that the Secretary may prescribe by regulation as consistent with the goals of this part.

(10) *Disclosure to law enforcement.*

(i) Disclosure of patient safety work product to an appropriate law enforcement authority relating to an event that either constitutes the commission of a crime, or for which the disclosing person reasonably believes constitutes the commission of a crime, provided that the disclosing person believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

(ii) Law enforcement personnel receiving patient safety work product pursuant to paragraph (b)(10)(i) of this section may disclose that patient safety work product to other law enforcement authorities as needed for law enforcement activities related to the event that gave rise to the disclosure under paragraph (b)(10)(i) of this section.

(c) *Safe harbor.* A provider or responsible person, but not a PSO, is not considered to have violated the requirements of this subpart if a member of its workforce discloses patient safety work product, provided that the disclosure does not include materials, including oral statements, that:

(1) Assess the quality of care of an identifiable provider; or

(2) Describe or pertain to one or more actions or failures to act by an identifiable provider.

(d) *Implementation and Enforcement of the Patient Safety Act.* The confidentiality provisions shall not apply to (and shall not be construed to

prohibit) disclosures of relevant patient safety work product to or by the Secretary if such patient safety work product is needed to investigate or determine compliance with this part or is needed in seeking and imposing civil money penalties, or in making or supporting PSO certification or listing decisions, under the Patient Safety Act.

(e) *No limitation on authority to limit or delegate disclosure or use.* Nothing in subpart C of this part shall be construed to limit the authority of any person to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this subpart.

§ 3.208 Continued protection of Patient Safety Work Product.

(a) Except as provided in paragraph (b) of this section, patient safety work product disclosed in accordance with this subpart, or disclosed impermissibly, shall continue to be privileged and confidential.

(b)(1) Patient safety work product disclosed for use in a criminal proceeding pursuant to section 922(c)(1)(A) of the Public Health Service Act and/or pursuant to § 3.206(b)(1) of this subpart continues to be privileged, but is no longer confidential.

(2) Non-identifiable patient safety work product that is disclosed is no longer privileged or confidential and not subject to the regulations under this part.

(3) Paragraph (b) of this section applies only to the specific patient safety work product disclosed.

§ 3.210 Required disclosure of Patient Safety Work Product to the Secretary.

Providers, PSOs, and responsible persons must disclose patient safety work product upon request by the Secretary when the Secretary determines such patient safety work product is needed to investigate or determine compliance with this part or is needed in seeking and imposing civil money penalties or making determinations on certifying and listing PSOs.

§ 3.212 Nonidentification of Patient Safety Work Product.

(a) Patient safety work product is nonidentifiable with respect to a particular identified provider or a particular identified reporter if:

(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an identified provider or reporter; and

(ii) Documents the methods and results of the analysis that justify such determination; or

(2)(i) The following identifiers of such provider or reporter and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members of such providers or reporters are removed:

(A) Names;

(B) Geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census, the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people;

(C) All elements of dates (except year) for dates directly related to a patient safety incident or event;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers or taxpayer identification numbers;

(H) Provider or practitioner credentialing or DEA numbers;

(I) National provider identification number;

(J) Certificate/license numbers;

(K) Web Universal Resource Locators (URLs);

(L) Internet Protocol (IP) address numbers;

(M) Biometric identifiers, including finger and voice prints;

(N) Full face photographic images and any comparable images; and,

(O) Any other unique identifying number, characteristic, or code except as permitted for re-identification; and

(ii) The provider, PSO or responsible person making the disclosure does not have actual knowledge that the information could be used, alone or in combination with other information that is reasonably available to the intended recipient, to identify the particular provider or reporter.

(3) *Re-identification.* A provider, PSO, or responsible person may assign a code or other means of record identification to allow information made nonidentifiable under this section to be re-identified by such provider, PSO, or responsible person, provided that:

(i) The code or other means of record identification is not derived from or related to information about the provider or reporter and is not otherwise capable of being translated so as to identify the provider or reporter; and

(ii) The provider, PSO, or responsible person does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

(b) Patient safety work product is non-identifiable with respect a particular patient only if the individually identifiable health information regarding that patient is de-identified in accordance with the HIPAA Privacy Rule standard and implementation specifications for the de-identification at 45 CFR 164.514 (a) through (c).

Subpart D—Enforcement Program

§ 3.304 Principles for achieving compliance.

(a) *Cooperation.* The Secretary will, to the extent practicable, seek the cooperation of providers, PSOs, and responsible persons in obtaining compliance with the applicable confidentiality provisions.

(b) *Assistance.* The Secretary may provide technical assistance to providers, PSOs, and responsible persons to help them comply voluntarily with the applicable confidentiality provisions.

§ 3.306 Complaints to the Secretary.

(a) *Right to file a complaint.* A person who believes that patient safety work product has been disclosed in violation of the confidentiality provisions may file a complaint with the Secretary.

(b) *Requirements for filing complaints.* Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the person that is the subject of the complaint and describe the act(s) believed to be in violation of the applicable confidentiality provision(s).

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act complained of occurred, unless this time limit is waived by the Secretary for good cause shown.

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the **Federal Register**.

(c) *Investigation.* The Secretary may investigate complaints filed under this section. Such investigation may include

a review of the pertinent policies, procedures, or practices of the respondent and of the circumstances regarding any alleged violation. At the time of initial written communication with the respondent about the complaint, the Secretary will describe the act(s) that are the basis of the complaint.

§ 3.308 Compliance reviews.

The Secretary may conduct compliance reviews to determine whether a respondent is complying with the applicable confidentiality provisions.

§ 3.310 Responsibilities of respondents.

(a) *Provide records and compliance reports.* A respondent must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the respondent has complied or is complying with the applicable confidentiality provisions.

(b) *Cooperate with complaint investigations and compliance reviews.* A respondent must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of the respondent to determine whether it is complying with the applicable confidentiality provisions.

(c) *Permit access to information.* (1) A respondent must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including patient safety work product, that are pertinent to ascertaining compliance with the applicable confidentiality provisions. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a respondent must permit access by the Secretary at any time and without notice.

(2) If any information required of a respondent under this section is in the exclusive possession of any other agency, institution, or person, and the other agency, institution, or person fails or refuses to furnish the information, the respondent must so certify and set forth what efforts it has made to obtain the information.

§ 3.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution when noncompliance is indicated.* (1) If an investigation of a complaint pursuant to § 3.306 of this subpart or a compliance review pursuant to § 3.308 of this subpart indicates noncompliance, the Secretary may attempt to reach a resolution of the matter satisfactory to the Secretary by informal means. Informal means may include demonstrated compliance or a completed corrective action plan or other agreement.

(2) If the matter is resolved by informal means, the Secretary will so inform the respondent and, if the matter arose from a complaint, the complainant, in writing.

(3) If the matter is not resolved by informal means, the Secretary will—

(i) So inform the respondent and provide the respondent an opportunity to submit written evidence of any mitigating factors. The respondent must submit any evidence to the Secretary within 30 days (computed in the same manner as prescribed under § 3.504(l) of this subpart) of receipt of such notification; and

(ii) If, following action pursuant to paragraph (a)(3)(i) of this section, the Secretary decides that a civil money penalty should be imposed, inform the respondent of such finding in a notice of proposed determination in accordance with § 3.420 of this subpart.

(b) *Resolution when no violation is found.* If, after an investigation pursuant to § 3.306 of this subpart or a compliance review pursuant to § 3.308 of this subpart, the Secretary determines that further action is not warranted, the Secretary will so inform the respondent and, if the matter arose from a complaint, the complainant, in writing.

(c) *Uses and disclosures of information obtained.* (1) Identifiable patient safety work product obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except in accordance with § 3.206(d) of this subpart, or if otherwise permitted by this part or the Patient Safety Act.

(2) Except as provided for in paragraph (c)(1) of this section, information, including testimony and other evidence, obtained by the Secretary in connection with an investigation or compliance review under this subpart may be used by HHS in any of its activities and may be used or offered into evidence in any administrative or judicial proceeding.

§ 3.314 Investigational subpoenas and inquiries.

(a) The Secretary may issue subpoenas in accordance with 42 U.S.C. 405(d) and (e), and 1320a–7a(j), to require the attendance and testimony of witnesses and the production of any other evidence including patient safety work product during an investigation or compliance review pursuant to this part. The Secretary will issue and serve subpoenas pursuant to this subpart in accordance with 45 CFR 160.314(a)(1) through (5), except the term ''this part'' shall refer to 42 CFR part 3.

(b) Investigational inquiries are non-public investigational proceedings conducted by the Secretary. The Secretary will conduct investigational proceedings in accordance with 45 CFR 160.314(b)(1) through (9).

§ 3.402 Basis for a civil money penalty.

(a) *General rule.* A person who discloses identifiable patient safety work product in knowing or reckless violation of the confidentiality provisions shall be subject to a civil money penalty for each act constituting such violation.

(b) *Violation attributed to a principal.* A principal is independently liable, in accordance with the federal common law of agency, for a civil money penalty based on the act of the principal's agent, including a workforce member, acting within the scope of the agency if such act could give rise to a civil money penalty in accordance with § 3.402(a) of this subpart.

§ 3.404 Amount of a civil money penalty.

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section and § 3.408 of this subpart.

(b) The Secretary may impose a civil money penalty in the amount of not more than $10,000.

§ 3.408 Factors considered in determining the amount of a civil money penalty.

In determining the amount of any civil money penalty, the Secretary may consider as aggravating or mitigating factors, as appropriate, any of the following:

(a) The nature of the violation.

(b) The circumstances, including the consequences, of the violation, including:

(1) The time period during which the violation(s) occurred; and

(2) Whether the violation caused physical or financial harm or reputational damage;

(c) The degree of culpability of the respondent, including:

(1) Whether the violation was intentional; and

(2) Whether the violation was beyond the direct control of the respondent.

(d) Any history of prior compliance with the Patient Safety Act, including violations, by the respondent, including:

(1) Whether the current violation is the same or similar to prior violation(s);

(2) Whether and to what extent the respondent has attempted to correct previous violations;

(3) How the respondent has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the respondent has responded to prior complaints.

(e) The financial condition of the respondent, including:

(1) Whether the respondent had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the respondent to continue to provide health care or patient safety activities; and

(3) The size of the respondent.

(f) Such other matters as justice may require.

§ 3.414 Limitations.

No action under this subpart may be entertained unless commenced by the Secretary, in accordance with § 3.420 of this subpart, within 6 years from the date of the occurrence of the violation.

§ 3.416 Authority to settle.

Nothing in this subpart limits the authority of the Secretary to settle any issue or case or to compromise any penalty.

§ 3.418 Exclusivity of penalty.

(a) Except as otherwise provided by paragraph (b) of this section, a penalty imposed under this part is in addition to any other penalty prescribed by law.

(b) Civil money penalties shall not be imposed both under this part and under the HIPAA Privacy Rule (45 CFR parts 160 and 164).

§ 3.420 Notice of proposed determination.

(a) If a penalty is proposed in accordance with this part, the Secretary must deliver, or send by certified mail with return receipt requested, to the respondent, written notice of the Secretary's intent to impose a penalty. This notice of proposed determination must include:

(1) Reference to the statutory basis for the penalty;

(2) A description of the findings of fact regarding the violations with respect to which the penalty is proposed;

(3) The reason(s) why the violation(s) subject(s) the respondent to a penalty;

(4) The amount of the proposed penalty;

(5) Any factors described in § 3.408 of this subpart that were considered in determining the amount of the proposed penalty; and

(6) Instructions for responding to the notice, including a statement of the respondent's right to a hearing, a statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty without the right to a hearing under § 3.504 of this subpart or a right of appeal under § 3.504(v) of this subpart, and the address to which the hearing request must be sent.

(b) The respondent may request a hearing before an ALJ on the proposed penalty by filing a request in accordance with § 3.504 of this subpart.

§ 3.422 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by § 3.504 of this subpart and the matter is not settled pursuant to § 3.416 of this subpart, the Secretary may impose the proposed penalty or any lesser penalty permitted by 42 U.S.C. 299b–21 through 299b–26. The Secretary will notify the respondent by certified mail, return receipt requested, of any penalty that has been imposed and of the means by which the respondent may satisfy the penalty, and the penalty is final on receipt of the notice. The respondent has no right to appeal a penalty under § 3.504(v) of this subpart with respect to which the respondent has not timely requested a hearing.

§ 3.424 Collection of penalty.

Once a determination of the Secretary to impose a penalty has become final, the penalty will be collected by the Secretary in accordance with 45 CFR 160.424, except the term ''this part'' shall refer to 42 CFR Part 3.

§ 3.426 Notification of the public and other agencies.

Whenever a proposed penalty becomes final, the Secretary will notify, in such manner as the Secretary deems appropriate, the public and the following organizations and entities thereof and the reason it was imposed: The appropriate State or local medical or professional organization, the appropriate State agency or agencies administering or supervising the administration of State health care programs (as defined in 42 U.S.C. 1320a–7(h)), the appropriate utilization and quality control peer review organization, and the appropriate State or local licensing agency or organization (including the agency specified in 42 U.S.C. 1395aa(a), 1396a(a)(33)).

§ 3.504 Procedures for hearings.

(a) *Hearings before an ALJ.* A respondent may request a hearing before an ALJ. Hearings must be requested in accordance with 45 CFR 160.504(a) through (c), except the language in paragraph (c) following and including ''except that'' shall not apply. The ALJ must dismiss a hearing request in accordance with 45 CFR 160.504(d).

(b) *Rights of the parties.* The hearing rights of the parties will be determined in accordance with 45 CFR 160.506.

(c) *Authority of the ALJ.* The ALJ will conduct a fair and impartial hearing in accordance with 45 CFR 160.508(a) through (c)(4).

(d) *Ex parte contacts.* Ex parte contacts are prohibited in accordance with 45 CFR 160.510.

(e) *Prehearing conferences.* Prehearing conferences will be conducted in accordance with 45 CFR 160.512, except the term ''identifiable patient safety work product'' shall apply in place of the term ''individually identifiable health information.''

(f) *Authority to settle.* The Secretary has authority to settle issues in accordance with 45 CFR 160.514.

(g) *Discovery.* Discovery will proceed in accordance with 45 CFR 160.516.

(h) *Exchange of witness lists, witness statements, and exhibits.* The parties will exchange hearing material in accordance with 45 CFR 160.518, except the language in paragraph (a) following and including ''except that'' shall not apply.

(i) *Subpoenas for attendance at hearing.* The ALJ will issue a subpoena for the appearance and testimony of any person at the hearing in accordance with 45 CFR 160.520.

(j) *Fees.* Fees and mileage for subpoenaed witnesses will be paid in accordance with 45 CFR 160.522.

(k) *Form, filing, and service of papers.* Hearing documents will be filed and serviced in accordance with 45 CFR 160.524.

(l) *Computation of time.* Computation of time shall be in accordance with 45 CFR 160.526, except the term ''this subpart'' shall refer to 42 CFR part 3, Subpart D, and the citation ''§ 3.504(a) of 42 CFR part 3'' shall apply in place of the citation ''§ 160.504.''

(m) *Motions.* Procedures for the filing and disposition of motions will be in accordance with 45 CFR 160.528.

(n) *Sanctions.* The ALJ may sanction a person in accordance with authorities at 45 CFR 160.530.

(o) *Collateral estoppel.* Collateral estoppel will apply to hearings conducted pursuant to this subpart in accordance with 45 CFR 160.532, except the term ''a confidentiality provision'' shall apply in place of the term ''an administrative simplification provision.''

(p) *The hearing.* Hearings will be conducted in accordance with 45 CFR

160.534, except the following text shall apply in place of § 160.534(b)(1): ''The respondent has the burden of going forward and the burden of persuasion with respect to any challenge to the amount of a proposed penalty pursuant to §§ 3.404–3.408 of 42 CFR part 3, including any factors raised as mitigating factors.'' Good cause shown under 45 CFR 160.534(c) may be that identifiable patient safety work product has been introduced into evidence or is expected to be introduced into evidence.

(q) *Witnesses.* The testimony of witnesses will be handled in accordance with 45 CFR 160.538, except that the citation ''§ 3.504(h) of 42 CFR part 3'' shall apply in place of the citation ''§ 160.518.''

(r) *Evidence.* The ALJ will determine the admissibility of evidence in accordance with 45 CFR 160.540, except that the citation ''§ 3.420 of 42 CFR part 3'' shall apply in place of the citation ''§ 160.420 of this part.''

(s) *The record.* The record of the hearing will be created and made available in accordance with 45 CFR 160.542. Good cause under 45 CFR 160.542(c) through (d) may include the presence in the record of identifiable patient safety work product.

(t) *Post hearing briefs.* Post-hearing briefs, if required by the ALJ, will be filed in accordance with 45 CFR 160.544.

(u) *ALJ's decision.* The ALJ will issue a decision in accordance with 45 CFR 160.546, except the citation ''§ 3.504(v) of 42 CFR part 3'' shall apply in place of ''§ 160.548.''

(v) *Appeal of the ALJ's decision.* Any party may appeal the decision of the ALJ in accordance with 45 CFR 160.548, except the following language in paragraph (e) shall not apply: ''Except for an affirmative defense under § 160.410(b)(1) of this part.''

(w) *Stay of the Secretary's decision.* Pending judicial review, a stay of the Secretary's decision may be requested in accordance with 45 CFR 160.550.

(x) *Harmless error.* Harmless errors will be handled in accordance with 45 CFR 160.552.

Dated: October 5, 2007.

Michael O. Levitt,

Secretary.

[FR Doc. E8–2375 Filed 2–11–08; 8:45 am]

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S. 2110/P.L. 110–184

To designate the facility of the United States Postal Service located at 427 North Street in Taft, California, as the ''Larry S. Pierce Post Office''. (Feb. 6, 2008; 122 Stat. 612)

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